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This opinion is not binding precedent of the Board

Paper No. 224

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

GEOFFREY S. MARTIN and JONATHAN E. LAST,
Junior Party,[1]

v.

ZYBLUT J. TWARDOWSKI, JOHN C. VAN STONE,
and W. KIRT NICHOLS,

Senior Party.[2]

Patent Interference No. 103,988

FINAL DECISION UNDER 37 CFR § 1.658

Before URYNOWICZ, PATE, and MARTIN, Administrative Patent Judges.

MARTIN, Administrative Patent Judge.

The subject matter of this interference is a flexible dual-lumen catheter for patients who require repeated hemodialysis

[1] Patent 5,156,592, issued October 20, 1992, based on Application 07/680,449, filed April 4, 1991. PTO assignment records show a 1991 assignment to Vas-Cath Incorporated (Canada); Martin's opening brief (at ii) identifies C.R. Bard as the assignee. Upon declaration of the interference, accorded the benefit as to Count 1 of: Canadian Application No. 2,013,877, filed April 4, 1990.

[2] Application 08/412,114, filed March 28, 1995. Assigned to The Curators of the University of Missouri. Upon declaration of the interference, accorded the benefit as to Count 1 of the following three U.S. Applications: 08/045,016, filed April 8, 1993 (now Patent 5,405,320, issued April 11, 1995); 07/772,613, filed October 8, 1991 (now Patent 5,209,723, issued May 11, 1993); and 07/461,684, filed January 8, 1990 (abandoned).

treatments over an extended period of time. At least a portion of the catheter is manufactured to have, in its unstressed condition prior to insertion into a patient, a curvature resembling the shape the catheter will have while in use in the patient. The issues before us include priority and the patentability of Twardwoski et al.'s involved claims.

We conclude that judgment should be entered in favor of Twardowski's involved claims and against Martin et al.'s involved claims.

A. BACKGROUND

The interference was initiated by applicants Twardowski et al. (Twardowski). Claim 19 of Twardowski's involved Application 08/412,114 (hereinafter "the involved Twardowski application")[3] is an exact copy of claim 1 of Martin et al.'s (Martin's) involved Patent No. 5,156,592 ("the Martin '592 patent")(MX A).[4]

The interference was declared on the basis of a single count, Count 1, which is a copy of Martin's claim 1 and Twardowski's identical claim 19.

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[3] A copy of Twardowski's involved claims is provided as Appendix A to this decision. A copy of the originally filed claims in the Twardowski application constitutes Appendix B.

[4] Hereinafter, the terms "MBr.," "TBr.," and "MRBr." refer to Martin's opening brief, Twardowski's amended opening brief, and Martin's reply brief. "MX" and "TX" refer to the parties' exhibits. "MR" and "TR" refer to the parties' records.

In the "Decisions on Motions"[5] (hereinafter "Motions Decisions"), the Administrative Patent Judge (APJ) denied Martin's Motions F and G to replace Count 1 with either of proposed Counts I and II (Motions Decisions at 54-55) and dismissed on procedural grounds Twardowski's counter-proposal to replace Count 1 with a proposed Count III that is the alternative combination of Twardowski's independent claims 1 and 38. Instead, the APJ sua sponte replaced Count 1 with Count 2 (reproduced infra at pages 56-57), which is the alternative combination of Twardowski's independent claims 1, 19, and 38 (of which claim 19 is a copy of Martin's claim 1) so that the count is broad enough to encompass all of the claims that are patentable over the prior art and designated as corresponding to the count (Motions Decisions at 55; Redeclaration letter[6]). The claims which are currently designated as corresponding to Count 2 are Martin's patent claims 1-19 and Twardowski's application claims 1 and 19-38. All of these claims except Martin's claim 19 were designated as corresponding to Count 1 when the interference was initially declared. That claim was sua sponte designated as

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[5] Paper No. 126.

[6] Paper No. 127, entitled "Redeclaration."

corresponding to Count 2 by the APJ (Motions Decisions at 56; Redeclaration letter).

Neither party takes issue with the APJ's substitution of Count 2 for Count 1 or sua sponte addition of Martin's claim 19 to the interference.

B. THE ISSUES AT FINAL HEARING

Martin seeks review of the following two decisions:

(a) the denial of Martin's Motion A alleging that Twardowski's claims 19-37 are unpatentable under 35 U.S.C. § 135(b) (Motions Decisions at 18-41); and

(b) the denial of Martin's Motion C alleging that Twardowski's claims 19-38 fail to satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1 (Motions Decisions at 47-51; Decision Denying Martin's Request for Reconsideration[7] at 1-10).

As these motions were denied on the merits rather than being dismissed on procedural grounds, no deference will be accorded to the APJ's reasons for denying the motions. See Consideration of Interlocutory Rulings at Final Hearing in Interference Proceedings, 64 Fed. Reg. 12,900, 12,901 (March 16, 1999)[8] (amending § 1.655(a) to make it clear that a Board panel at final

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[7] Paper No. 133.

[8] This notice was not reported in the United States Patents Quarterly (2d ed.).

hearing will resolve the merits of an interference (e.g., patentability or an attempt to obtain the benefit of an earlier application) without giving deference to any interlocutory order[9] and will apply the abuse of discretion standard to any interlocutory procedural orders, such as the dismissal of a motion for failing to comply with the rules). Accordingly, the merits of the denied motions will be addressed de novo. The burden of proof with respect to all motions lies with the moving party. 37 CFR § 1.637(a); Kubota v. Shibuya, 999 F.2d 517, 520-21, 27 USPQ2d 1418, 1421 (Fed. Cir. 1993). Arguments made in the motions which are not repeated in the briefs will be regarded as abandoned. Irikura v. Petersen, 18 USPQ2d 1362, 1365 n.6 (Bd. Pat. App. & Int. 1990).

Martin also seeks review of the APJ's "Decision dismissing Martin's motion to consider Canadian Patent No. 1,150,122."[10] In that motion,[11] which stated it was filed under "§ 1.621 et. seq.," Martin requested the APJ to exercise his discretion under

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[9] 37 CFR § 1.601(q)(2002) provides: "A final decision is a decision awarding judgment as to all counts. An interlocutory order is any other action taken by an administrative patent judge or the Board in an interference, including the notice declaring an interference." Except where otherwise noted, all references hereinafter to the Code of Federal Regulations are to the 2002 edition.

[10] Paper No. 142.

[11] Paper No. 136.

§ 1.641 to consider whether Twardowski's claims are unpatentable over the Canadian '122 patent, which names Geoffrey Martin as the inventor.

Twardowski does not seek review of any motion decisions.

Both parties have filed priority evidence and have moved to suppress some of the their opponent's testimony and documents.

Counsel for both parties appeared at the final hearing on May 13, 2003.

C. CONSTRUCTION OF TWARDOWSKI'S INVOLVED CLAIMS

The principal issue before us is the meaning of the term "generally U-shape" in the phrase "said catheter defining an arc angle of generally U-shape in its natural, unstressed configuration." This language appears in Twardowski's claim 1 and the identically worded Alternative A of Count 2. Because we will consider the patentability issues before reaching priority, we will first address how to construe the foregoing language in Twardowski's claim 1, which reads:[12]

> 1. A catheter for hemodialysis which comprises a flexible catheter tube defining a plurality of separate lumens, said catheter defining an arc angle of generally U-shape in its natural, unstressed configuration, whereby said catheter may be implanted with a distal catheter portion residing in a vein of a

[12] The construction of this language in Alternative A of Count 2 is addressed infra in the discussion of Martin's priority case.

> patient, said distal catheter portion being of substantially the shape of said vein in its natural, unstressed condition, and a proximal catheter portion residing in a surgically created tunnel extending from said vein and through the skin of the patient, whereby blood may be removed from said vein through one lumen of the catheter and blood may be returned to said vein through another lumen of the catheter.

Insofar as patentability issues raised in motions under 37 CFR § 1.633(a) are concerned, the terminology of involved claims is to be construed in light of the associated disclosures. 37 CFR § 1.633(a); Rowe v. Dror, 112 F.3d 473, 479 & n.2, 42 USPQ2d 1550, 1554 & n.2 (Fed. Cir. 1997). Furthermore, application claims must be given the broadest reasonable interpretation consistent with their associated disclosure. As explained in In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989),

> [d]uring patent examination the pending claims must be interpreted as broadly as their terms reasonably allow. When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. See In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969) (before the application is granted, there is no reason to read into the claim the limitations of the specification). The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. Burlington Industries, Inc. v. Quigg, 822 F.2d 1581, 1583, 3 USPQ2d 1436, 1438 (Fed. Cir. 1987); In re Yamamoto, 740 F.2d 1569, 1571, 222 USPQ 934, 936 (Fed. Cir. 1984). The issued claims are the measure of the

> protected right. United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 232, 55 USPQ 381, 383-84 (1942) (citing General Electric Corp. v. Wabash Appliance Corp., 304 U.S. 364, 369, 37 USPQ 466, 468-69 (1938)).

See also In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997):

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

The ordinary meaning of a claim term can be ascertained from standard dictionaries, encyclopedias, and treatises. See In re Ripper, 171 F.2d 297, 299, 80 USPQ 96, 98 (CCPA 1948)("[I]t is clear that in ascertaining the meaning of [the claim term] as it appears herein, reference properly may be made to the ordinary dictionaries."); Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202, 64 USPQ2d 1812, 1818 (Fed. Cir. 2002)("It has been long recognized in our precedent and in the precedent of our predecessor court, the Court of Customs and Patent Appeals, that dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms."). However, reference to such sources is unnecessary in the present case because the ordinary meaning of the phrase "generally U-shape" is self-

evident: it refers to a shape consisting of a pair of laterally spaced, at least approximately parallel leg portions having their respective first ends joined together by a connecting portion, which may be curved or straight. The requirement that the leg portions be at least approximately parallel can also be described as a requirement that the leg portions point in at least approximately the same direction. Furthermore, the claim language in question is broad enough to read on a catheter that is generally U-shaped either in whole or in part.

Nothing in Twardowski's application as filed (MX U) suggests that the term "generally U-shape" should be construed as broad enough to read on a precurved catheter or catheter region having leg portions pointing in nearly perpendicular directions, as argued by Twardowski, or on any preformed curved portion of a catheter, as argued by Martin. To the contrary, the Twardowski specification employs the terms "generally U-shaped" and "substantially U-shape" to describe only two catheters, both of which have end portions pointing in directions that are separated by an angle of no more than twenty degrees. The first of these two catheters is the right jugular catheter shown in Figures 9 and 10, of which only Figure 9 is reproduced below:

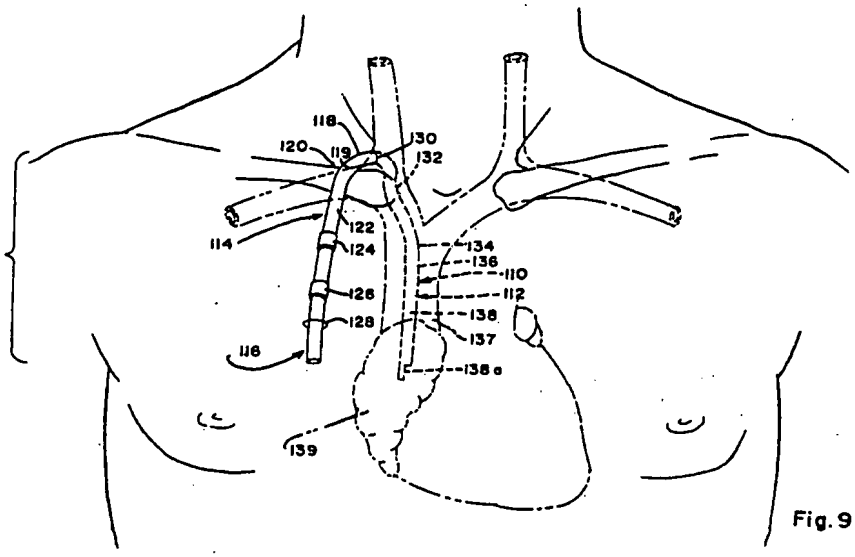

Fig. 9

This catheter, which has a bent section 118 "typically defin[ing] an arc angle[13] of 160-180°" (Specification at 26, ll. 23-25), is described as being "of substantially U-shape" (id. at 28,

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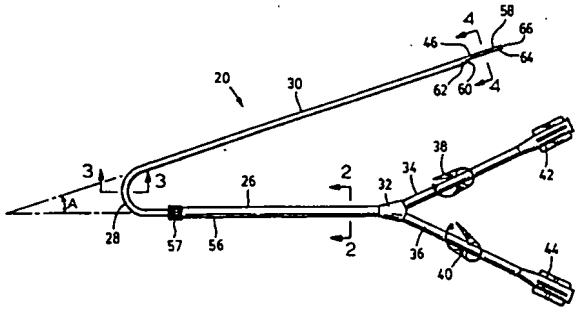
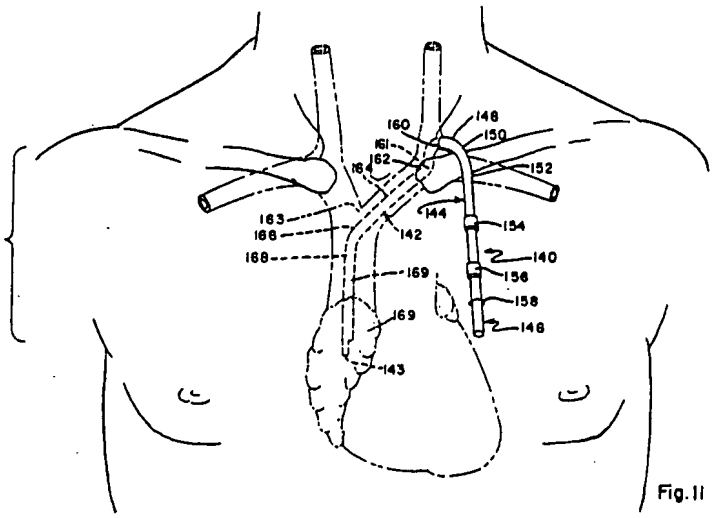
[13] Twardowski's "arc angle" is the complement of the interior angle between the distal and proximal portions of the catheter, which interior angle is identified as angle A in Martin's Figure 1:



ll. 10-13). Thus, the term "substantially U-shape" is applied to this catheter as a whole.

The second catheter is the left jugular catheter shown in Figures 11 and 12 (only Figure 11 is shown below), which is described as having "a bent, generally U-shaped section 148 which . . . typically defines an arc angle of 160-180°" (id. at 29, ll. 2-4).



Thus, the term "generally U-shaped," which we consider to be equivalent to the "substantially U-shape[d]" terminology applied to the Figure 9 catheter, is applied to only the bent section 148 of the Figure 11 catheter.

Although Twardowski's application does not use the term "U-shape" or any variation thereof when describing the following

three additional catheters, it is evident that all of them are precurved in whole or in part so as to form leg portions pointing in directions no more than about twenty degrees apart, which is consistent with Twardowki's use of "substantially U-shape" and "generally U-shaped" to describe the catheters of Figures 9 and 11.

The first of these three catheters is the right jugular catheter shown in Figures 3 and 4 (only Figure 3 is reproduced below), which is described as "defin[ing] almost a 180 degree arc angle throughout section 58" (id. at 18, l. 25 to p. 19, l. 1):

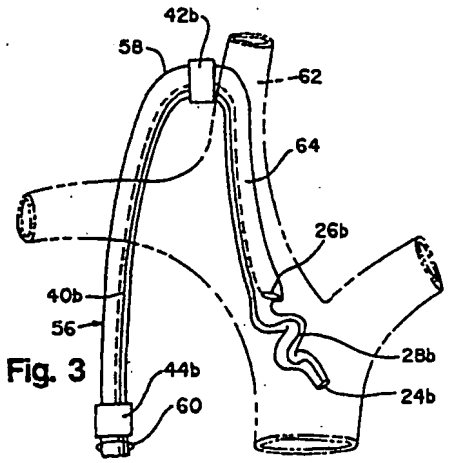


Fig. 3

The second of these three catheters is the right subclavian catheter shown in Figures 13 and 14 (only Figure 13 is shown below):

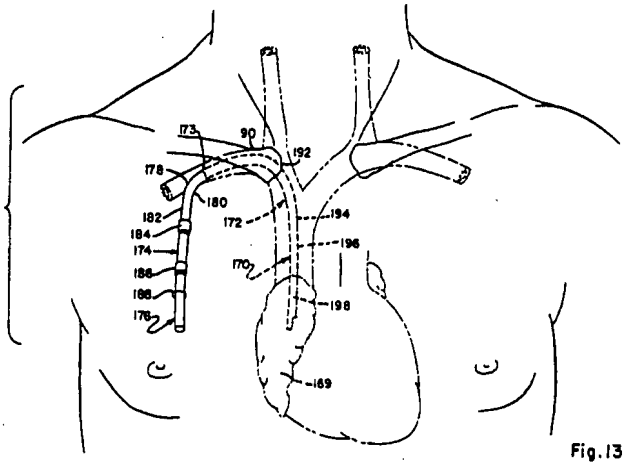


Fig.13

The third is the left subclavian catheter shown in Figures 15 and 16 (only Figure 15 is shown below):

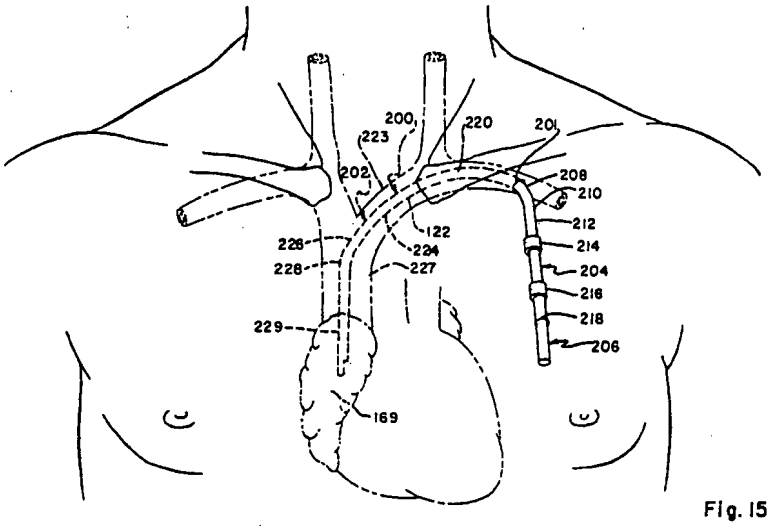
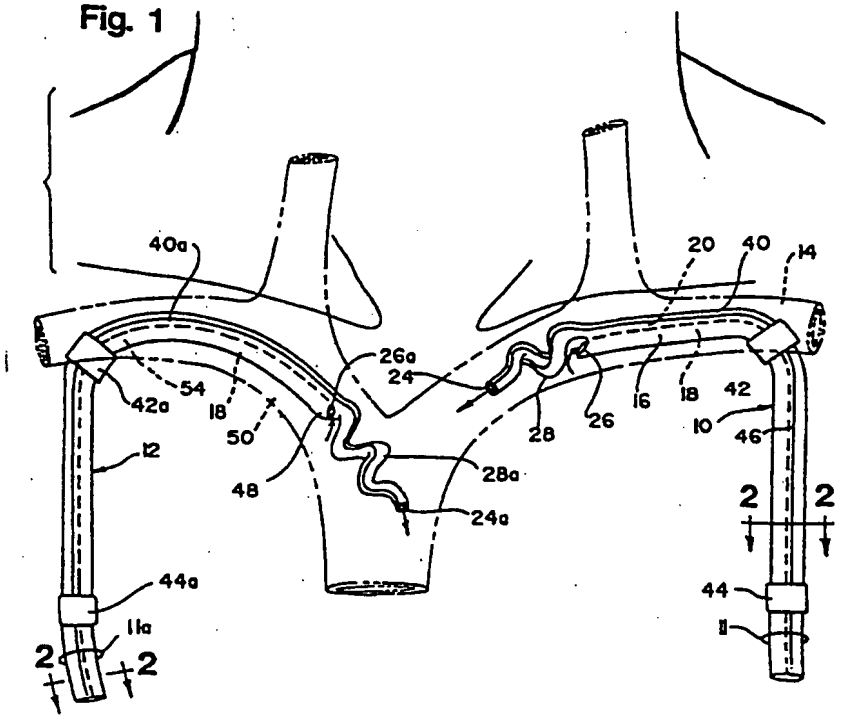


Fig. 15

We note that no party denies that all of the originally filed claims which directly or indirectly specify a generally U-shape,

i.e., independent claims 1 and 6 and dependent claims 2-5 and 7-12, can be read on one or more of the five jugular and subclavian catheters described above. Furthermore, while it is true that Twardowski's abstract broadly recites that "[t]he catheter defines an arc angle of generally U-shape in its natural, unstressed configuration" without limiting this characterization to any particular disclosed catheters, the abstract does not indicate that this characterization is intended to apply to catheters other than the five jugular and subclavian catheters described above.

It is also evident that the Twardowski specification does not treat the term "arc angle," which it also applies to other disclosed catheters, as synonymous with "generally U-shape." Thus, the specification describes catheter 10 in Figure 1 (reproduced below) as defining "an arc angle of approximately 90 degrees" (Specification at 14, ll. 15-19) and catheter 12 (also Figure 1) as defining "an arc angle of somewhat greater than 90 degrees" (id. at 18, ll. 16-21) without characterizing either catheter as being generally or substantially U-shaped:



Consequently, we cannot agree with Twardowski's contention (TBr. 38-39) that the term "generally U-shape" is broad enough to read on these two catheters.

Nor is Twardowski correct to assert (TBr. 38-39, ¶ 94) that the specification describes curved section 178 of the Figure 13 catheter (shown supra page 13) and curved section 208 of the Figure 15 catheter (also shown supra page 13) as defining arc angles of "generally U-shape." Instead, the specification simply describes curved section 178 of the Figure 13 catheter as "defining an arc angle of typically 70-100 degrees" (id. at 30, ll. 14-16) and the curved section 208 in the Figure 15 catheter

as "defin[ing] an arc angle of 70-130 degrees" (id. at 32, ll. 11-13) without characterizing either curved section as being generally or substantially U-shaped.

For the reasons given above, the Twardowski specification also fails to provide support for Martin's even broader position that "'generally U-shape in its natural, unstressed configuration' . . . means simply a preformed curved portion of a catheter" (MBr. 56).

The parties' broad interpretations of "generally U-shape" also lack factual support in the cited testimony[14] and exhibits. No witness asserted that any of the terms "U-shape," "generally

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[14] That the parties are entitled to present testimony regarding the meaning of the involved claims is clear. See Martin v. Mayer, 823 F.2d 500, 3 USPQ2d 1333 (Fed. Cir. 1987):

> In Philips [v. Matthews, 197 USPQ 776 (Bd. Pat. Int. 1977)] the Board held that although "expert testimony may not ordinarily be received for the purpose of explaining a disclosure" or to determine "the scope of the issue",
>
> > [o]n the other hand, just as a party may introduce dictionaries and textbooks for the purpose of establishing facts such as the meaning of various terms to those skilled in the art and the properties of various materials . . . so may he employ the testimony of an expert for that same purpose.
>
> Id. at 777-78. Doljack's testimony as to what the terms "wire", "cable", and "coaxial" meant to a person skilled in the art was of this character.
>
> Thus the Board erroneously excluded this evidence[.]

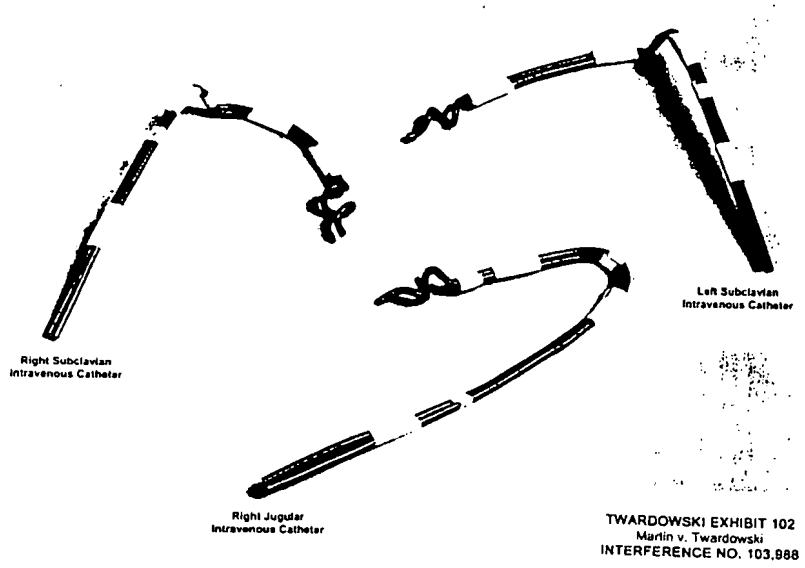
Martin, 823 F.2d at 504, 3 USPQ2d at 1336.

U-shape," or "substantially U-shape" have acquired a special meaning in the catheter art. Instead, the witnesses merely offer their unsupported opinions, which are entitled to no weight. Cf. Rohm & Haas Co. v. Brotech Corp., 127 F.3d 1089, 1092, 44 USPQ2d 1459, 1462 (Fed. Cir. 1997):

> While an expert may testify to the ultimate issue in a case without giving the basis for that opinion, Fed. R. Evid. 704, 705, nothing in the rules requires a fact finder to accept this conclusion. In Symbol Technologies [v. Opticon, Inc., 935 F.2d 1569, 19 USPQ2d 1241 (Fed. Cir. 1991)], this court explained the distinction between a proffer of evidence and the sufficiency of the proffered evidence: "In short, [the patentee] was permitted to rest its prima facie case on [the] expert testimony, including charts, that the patents were infringed, and the District Court was free to accept or reject that evidence." 935 F.2d at 1576. [19 USPQ2d at 1246.] Nothing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness.

See also In re Wright, 999 F.2d 1557, 1563, 27 USPQ2d 1510, 1514 (Fed. Cir. 1993)("each of these affidavits fails in its purpose because each merely contains unsupported conclusory statements as to the ultimate legal question"). Twardowski's witness Dr. Karl Nolph testified that "[t]o me, in the context of catheters, the term[] 'arc angle of generally U-shape' . . . describ[es] a catheter in which both ends are generally parallel or are pointing in the same general direction" (TR 140, ¶ 13), which appears to be consistent with our understanding of the ordinary meaning of "generally U-shape." However, he then asserts,

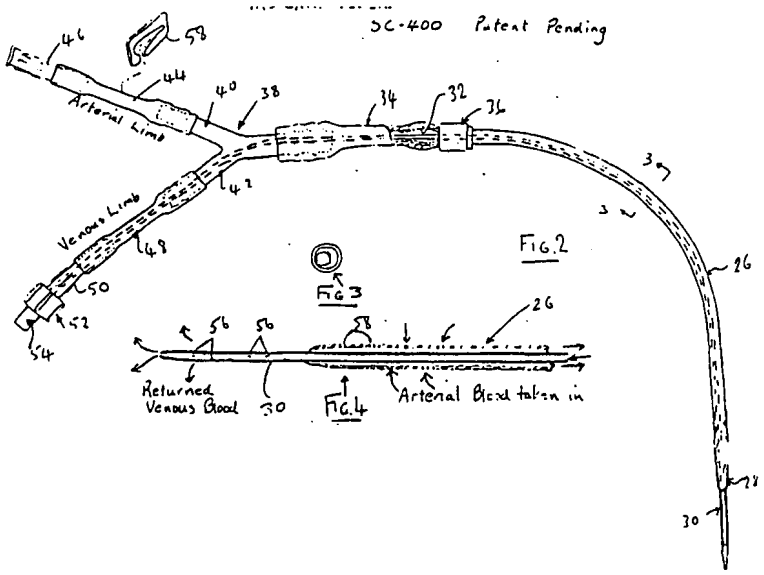
without factual or analytical support, that "pointing in the same general direction" is satisfied by distal and proximal end portions which "form an [interior] angle that is less than 90 degrees." Id. Likewise, Twardowski's witness Bradford Fowler, without providing any documentary or analytical support, describes as generally U-shaped all of the catheter prototypes made in the shapes of the three wire models shown in TX 102 (reproduced below)(Fowler Decl. ¶¶ 9, 12):[15]



In our view, only the bottom model can accurately be described as being "generally U-shaped" in whole or in part.

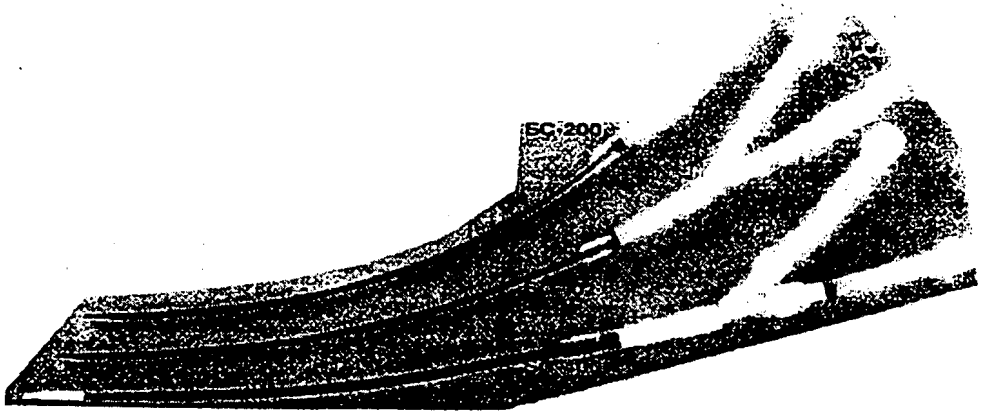
[15] None of the Twardowski et al. inventors offered any testimony on this or any other issue.

The testimony of Martin's witnesses on the interpretation issue likewise lacks sufficient factual support. This testimony includes Anand Ram's description of the Vas-Cath SC-400 catheter design shown in MX 6 (reproduced below) "as pre-curved so that it was generally U-shaped prior to insertion" (MR 31, ¶¶ 3, 4) and inventor Martin's testimony to the same effect (Martin Decl. B ¶¶ 4-5, MR 16).



The unsupported testimony also includes inventor Last's application of the term "generally U-shaped" to the commercial embodiment of the SC-400 catheter, which is the bottom catheter in the photograph of three catheters shown in a Shiley, Incorporated advertisement that accompanied 11 Dialysis &

Transplantation (August 1982)(TX 68) (Last Depo., MR 101, ll. 21-24; MR 107, l. 20 to MR 108, l. 2):



Nor is there any support for Dr. Quinton's opinion that "[a]ny bend in the catheter is generally U-shaped" (MR 138, ll. 11-12), that "any tube which is bent in a plane which is parallel to both ends of the tube is U-shaped" (MR 162, ll. 12-14, that a bend creating an arc angle of more than one degree is "U-shaped" (MR 181, ll. 14-16), and that "[a]ccording to my definition, anything that's not straight that is -- lies in one plane [--] is U-shaped" (MR 182, ll. 19-21). During his cross-examination, Dr. Quinton was asked (MR 147-60) to reconcile his broad interpretation of "generally U-shape" with the fact that the terms "U-shaped" and "generally U-shaped" are used in Martin U.S. Patent 5,350,358 (TX 88) and Martin U.S. Patent 5,324,274 (TX 89)

to describe the following catheters (Martin '358 at col. 2, ll. 21, 35, and 57; Martin '274 at col. 4, ll. 27-28):

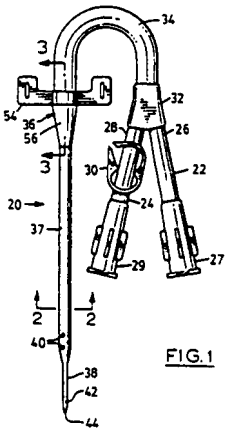


FIG. 1

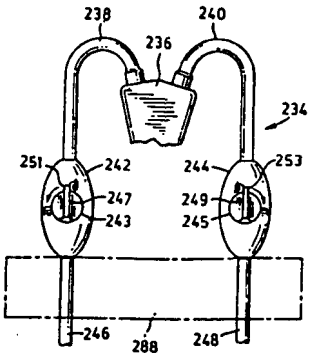


FIG. 4

Twardowski's brief (TBr. 38, ¶ 92) cites these patents and Dr. Quinton's testimony about the Martin '358 patent (Quinton Depo., MR 157, ll. 5-7) to show that Martin has previously used the term "generally U-shape" in other patents of his to describe bends in catheters approximating arc angles of 180 degrees. Martin has moved to suppress this evidence on the grounds that the exhibits (1) are outside the scope of Dr. Quinton's direct testimony, (2) lack authentication under Fed. R. Evid. 901, (3) are not within Dr. Quinton's personal knowledge under Fed. R. Evid. 602, and (4) contain inadmissible hearsay pursuant to Fed.

R. Evid. 801.[16] None of these objections are persuasive. The questions about these patents concern Dr. Quinton's understanding of the term "generally U-shape" as applied to catheters and thus are clearly within the scope of his direct testimony. Next, U.S. patents are self-authenticating under Fed. R. Evid. 902(5) ("Books, pamphlets, or other publications purporting to be issued by public authority"). Driekorn v. Barlow, 214 USPQ 632, 635 (Comm'r Pats. 1981). The objection that Dr. Quinton lacks personal knowledge fails because during his cross-examination he reviewed the parts about which he was asked to testify. The hearsay objection fails because these patents are relied on to show that the disclosed catheters are described therein as being generally U-shaped, not for the truth of that assertion. These patents (TX 88 and 89) and Dr. Quinton's testimony about them therefore will not be suppressed. However, this evidence is consistent with our interpretation of "generally U-shape" and thus do not provide support for either party's broader interpretation of that term.

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[16] The motion is dismissed as moot with respect to the following exhibits two exhibits because they are not relied on in Twardowski's brief: TX 91 (Martin U.S. Patent 5,395,316); and TX 92 (Dadson U.S. Patent 5,053,003). For the same reason, the motion is dismissed with respect to Dr. Quinton's testimony at MR 165, ll. 13-14 (cited at TBr. 38, ¶ 92), which concerns TX 91.

Martin additionally seeks to suppress the file history (TX 90) of the Martin '274 patent (TX 89). Page 20 and claim 3 of this file history are cited at TBr. 38, ¶ 92, as additional support for the contention that Martin has previously used the term "generally U-shape" in other patents to describe bends approximating arc angles of 180 degrees. The file history is not being suppressed but, like TX 88 and TX 89, it is consistent with our interpretation and thus fails to support either party's broader interpretation.[17]

For the foregoing reasons, we conclude that the recitation in Twardowski's claim 1 that the "catheter defin[e] an arc angle of generally U-shape in its natural, unstressed configuration" requires that the precurved catheter or catheter region have a pair of spaced leg portions which extend in at least approximately the same direction. The claim language therefore is not broad enough to read on a precurved catheter or catheter region have end portions which point in nearly perpendicular

[17] The motion to suppress is dismissed with respect to TX 91 (Martin U.S. Patent 5,395,316) and TX 92 (Dadson U.S. Patent 5,053,003) because these exhibits are not specifically relied on in Twardowski's brief. The requested suppression of TX 93 (excerpts from 13 Dialysis & Transplantation) (1984) will be addressed later, if necessary, because that document is not relied on in connection with the "generally U-shape" issue.

directions, as argued by Twardowski, let alone in nearly opposite directions, as argued by Martin.

D. THE ALLEGED UNPATENTABILITY OF TWARDOWSKI'S CLAIMS

(a) Whether Twardowski's claims 19-37 are unpatentable under 35 U.S.C. § 112, ¶ 1 (written description requirement)

Of claims 19-38, which Twardowski added for the purpose of initiating this interference, claims 19 and 38 are independent claims and claims 20-37 depend on claim 19.

Martin's Motion C, which the APJ denied,[18] argues that claims 19-37 lack written description support in the Twardowski application as filed because they do not require that the distal portion of the catheter in its natural, unstressed condition "be[] of substantially the shape of said vein [in which it is to reside]", as required by Twardowski's originally filed claim 1, reproduced supra at pages 6 and 7. Claim 19, which reads as follows, does not specify the shape of the distal portion of the catheter:

> 19. A flexible catheter for prolonged vascular access, the catheter comprising: an elongate flexible and tubular body having a proximal portion, a distal portion and a permanently curved portion linking the proximal and distal portions so that the curved, the proximal and the distal portions lie naturally in essentially the same plane with the angle contained between the proximal and distal portions being less than 90°, and a septum extending continuously through

[18] Motions Decisions at 47-51.

> said portions and lying substantially at right angles to said plane to divide the tubular body into generally D-shaped intake and outlet lumens; intake and outlet tubes coupled to the proximal portion at a proximal end of the body remote from the curved portion to receive incoming fluid from the intake lumen and to supply outgoing fluid to the outlet lumen; and a tip formed on the distal end of the distal portion and including at least one intake opening for receiving the incoming fluid and at least one outlet opening for returning the outgoing fluid.

We note that the language at issue in claim 1 does not necessarily require that the distal portion have some curvature in its natural, unstressed condition. Where the vein into which the distal catheter portion is to reside has very little curvature, as is the case with the left subclavian vein shown in Twardowski's Figure 1 (reproduced supra at page 15), which receives the distal portion 16 of catheter 10, a distal portion which is straight in its natural, unstressed condition will have "substantially the shape of said vein [in which it is to reside]." On the other hand, catheter 12 in Figure 1, which is intended for insertion into the right subclavian vein, must have some precurvature in its natural, unstressed condition if it is to have substantially the shape of that vein.

In any event, for the following reasons we are not persuaded that the Twardowski application as filed, considered as a whole, clearly indicates that the distal portion of the catheter in its natural, unstressed condition must have substantially the shape

of the vein in which it is to reside. See PIN/NIP Inc. v. Platte Chem. Co., 304 F.3d 1235, 1248, 64 USPQ2d 1344, 1352-53 (Fed. Cir. 2002):

> In Gentry Gallery, Inc. v. Berkline Corp., the patentee had amended its claims to a sectional sofa so as to remove a limitation that controls for a pair of parallel recliners be located on a console between the recliners. 134 F.3d 1475, 1478, 45 USPQ2d 1499, 1503 (Fed. Cir. 1998). We held that the broadened claims failed to satisfy the written description requirement because the written description clearly described the central console as the only location for the controls. Id. at 1479, 45 USPQ2d at 1502. "In Gentry, we applied and merely expounded upon the unremarkable proposition that a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope." Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc., 291 F.3d 1317, 1323, 62 USPQ2d 1846, 1851(Fed. Cir. 2002).

The Twardowski invention addresses the following clotting problems encountered when using flexible hemodialysis catheters of the type which are straight in their unstressed condition:

> Such catheters . . . are usually installed into the venous system in a substantially curved position. Thus, the elastic memory of these catheters causes them to press against some of the vein intima in certain places, with a resulting irritation thereof, and an increase in clotting potential. Likewise, it has been found that catheters which press against the vein walls also uncover vessel wall collage, which attract and activate platelets and the clotting system for an increase in clotting potential, which can cause catheter occlusion by clot attachment to the vein wall, subsequent fibrosis of the clot, and vein stenosis.

Twardowski Specification at 2, l. 26 to p. 3, l. 10. Several solutions are employed. The first is to design the distal end

portion of the catheter so that "[t]he outflow port of the catheter, where a suction is developed, is protected against engagement with the vein intima tissues and the like" (Twardowski specification at 3, ll. 12-15). This goal is accomplished by forming the distal end portion of the catheter between the outflow port and the inflow port as a helix (id. at 4, l. 9 to page 6, l. 1), as shown in Figure 1 (reproduced supra at page 15).

The second solution is to provide the catheter with "a desired, curved configuration in its as-manufactured, unstressed configuration, so that the catheter occupies its indwelling site with less irritation of the vein or duct walls, wherever the catheter may be emplaced" (id. at 3, ll. 16-20). We believe it is evident from the presence of the term "additional embodiment" in the third sentence of the following passage that the feature recited in that sentence (namely, precurving the distal portion of the catheter so as to conform to the shape of the receiving vein) is an optional addition to the feature recited in the first and second sentences (namely, providing the catheter with an angled portion, such as a generally U-shaped portion, which separates the distal and proximal portions):

> Also, the catheters of this invention preferably have a section thereof which defines an arc angle of at least about 90 degrees, and, if desired, up to about

> 180 degrees. This angled section is preferably spaced from and proximal to the second port. As [an] additional embodiment, a length of such a catheter which is positioned between the angled section and the second port defines an arc in the dimension perpendicular to the plane defined by the arc angle in the section. Both the angled section and the arc may be proportioned so that the flexible catheter, in its unstressed, as-manufactured configuration, can provide improved registry with the shape of the blood vessel in which the length of the catheter resides. Thus, such a catheter will exhibit less pressure and abrasion against the blood vessel walls, providing conditions under which less clotting and tissue irritation will take place. This, in turn, provides a catheter which is capable of long-term indwelling in the A.V. system of a patient.

(Emphasis added.) Id. at 6, ll. 2-18. The presence of "may" in the following passage further indicates the optional nature of distal precurvature:

> Further in accordance with this invention, catheters of the types described above, as well as other catheters, may be of specific, desired shapes as described below in their unstressed, as-manufactured configurations for obtaining the desired improved registry with the shape of the blood vessel in which the length of the catheter resides. Thus, such catheters exhibit less pressure and abrasion against the blood vessel walls for the advantages of reduction in clotting and tissue irritation as described above.

(Emphasis added.) Id. at 7, ll. 7-15.

That distal precurvature is optional is also evident from the different descriptions of catheters 10 and 12 of Figure 1, which depicts both catheters in their natural, unstressed condition (id. at 16, ll. 2-4; id. at 18, ll. 1-3). The

description of catheter 12 credits both the angled portion and the precurvature of the distal portion with minimizing vein wall contact:

> In the arced area generally indicated by reference numeral 54, catheter 12 defines an arc angle of somewhat greater than 90 degrees. This arc angle is predetermined, plus the curvature of the arc of the catheter between cuff 42a and second port 26a, to accommodate to the shape of vein 50 with minimal vein wall contact.

Id. at 18, ll. 16-21. On the other hand, the description of catheter 10 credits the angled section with reducing pressure against the vein without mentioning any precurvature of the distal portion:

> Catheter 10 extends through a surgically formed tissue tunnel from an entry port 11 at the skin, through to an aperture cut in vein 14, at which point catheter 10 defines an arc angle of approximately 90 degrees and a vein indwelling portion 16. [Twardowski specification at 14, lines 15-19.]
>
> . . . .
>
> [B]ecause catheter 10 defines an angled section, it can fit into vein without any significant plastic memory attempting to force the catheter into a straight configuration or the like, so that the distal portion 16 of the catheter resides in the vein with less pressure against the vein walls. [Id. at 16, lines 4-9.]

Although the distal portion of catheter 10 is depicted in Figure 1 with a very slight curvature, the failure of the specification to mention this curvature means it is entitled to

no weight. Cf. Hockerson-Halberstadt, Inc. v. Avia Group Int'l, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000):

> [I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue. See In re Wright, 569 F.2d 1124, 1127, 193 USPQ 332, 335 (CCPA 1977)("Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value."); In re Olson, 212 F.2d 590, 592, 101 USPQ 401, 402 (CCPA 1954); cf. Manual of Patent Examining Procedure § 2125 (1998).

Martin (MBr. 38, ¶¶ 47-48) cites the prosecution history (TX 29) of the Twardowski '320 patent, of which Twardowski's involved application was filed as a continuation, to show that precurvature of the distal portion was relied on to distinguish the Twardowski '320 claims from the prior art. This argument is entitled to no consideration because the '320 patent prosecution history was not cited in support of the motion even though it was available to Martin when Motion C was filed.[19] See Bayles v. Elbe, 16 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1990):

> It has been a long standing practice that a party whose motion was denied cannot present at final hearing reasons in favor of granting the motion if those reasons were not included in the original motion. Fredkin v. Irasek, 397 F.2d 342, 158 USPQ 280 . . . (CCPA), cert. denied, 393 U.S. 980 [159 USPQ 799]

[19] The '320 patent issued on April 11, 1995, more than two and one-half years prior to the December 19, 1997, filing date of the motion.

(1968); Koch v. Lieber, 141 F.2d 581, 61 USPQ 127 (CCPA 1944); Payet v. Swidler, 207 USPQ 168 at 171 (Bd. Pat. Int. 1980); Phillips v. Matthews, 197 USPQ 776 (Bd. Pat. Int. 1977).

Martin also relies on Twardowski's priority testimony and exhibits as evidence that the Twardowski inventors considered distal precurvature to be an essential part of their invention. Although this evidence was unavailable when Motion C was filed, it is entitled to no consideration because it was not cited in a belated § 1.633(a) motion offering it as additional proof of unpatentability. See Interference Practice: Matters Relating to Belated Preliminary Motions, 1144 Off. Gaz. Pat. Office 8, 8 (Nov. 3, 1992)(where evidence that provides a basis for a motion under 37 CFR 1.633(a) does not come to light until after the end of the preliminary motion period, the board will not consider the matter unless the party, promptly after the evidence becomes available, files a belated preliminary motion under § 1.633(a) and a motion under § 1.635 showing sufficient cause[20] under § 1.645(b) for the belatedness).

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[20] Effective April 21, 1995, the term "sufficient cause" in § 1.645(b) was changed to "good cause" to be consistent with the terminology used in other interference rules. Patent Appeal and Interference Practice -- Final Rule, 60 Fed. Reg. 14,488, 14,513 (March 17, 1995); 1173 Off. Gaz. Pat. & Trademark Office 36, 57 (April 11, 1995).

For the foregoing reasons, Martin's contention that the claims are unpatentable for lacking written description support in the Twardowski application as filed fails as to Twardowski's independent claim 19 and its dependent claims 20-37.

(b) Whether Twardowski's claims 19-37 are unpatentable under 35 U.S.C. § 135(b)

Twardowski's claims 19-38 were added on March 28, 1995, more than one year after the Martin '592 patent's October 20, 1992, issue date.[21]

The limitation at issue in Twardowski's claim 19 (reproduced supra at pages 24 and 25), which is an exact copy of Martin's claim 1, is "a septum extending continuously through said [curved, proximal, and distal] portions and lying substantially at right angles to said plane [containing the curved, proximal, and distal portions] to divide the tubular body into generally D-shaped intake and outlet lumens." Martin's concession that the recitation of "double-D lumens" without specifying a particular orientation is not a material limitation (MBr. 50 n.8) is consistent with the fact that Martin's involved '592 patent describes Martin's U.S. Patent No. 4,451,252 (TX 21) as "utiliz[ing] the well known dual lumen configuration in which the

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[21] Martin's Motion A arguing unpatentability of these claims under 35 U.S.C. § 135(b) was denied by the APJ at page 30 of the Motions Decisions.

lumens are arranged side-by-side separated by a diametric septum" (TX 21 at col. 2, ll. 45-50). The septum and double-D lumens of the Martin '252 catheter, which is flexible (id. at col. 2, ll. 51-55) but not precurved, are shown in cross section in Figure 5:

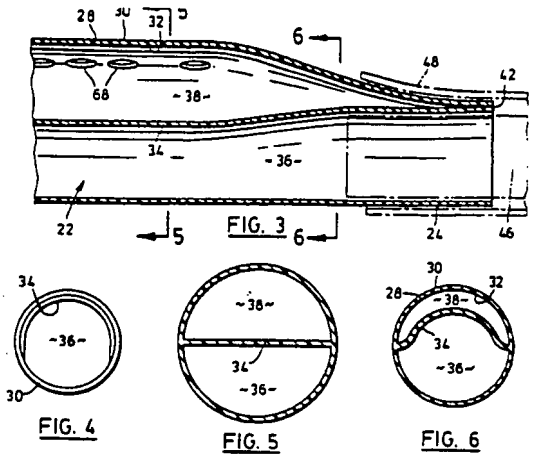

FIG. 3

FIG. 4

FIG. 5

FIG. 6

Thus, we understand Martin's argument to be that the claimed right-angle orientation of the diametric septum relative to the plane of the bend in the catheter (hereinafter referred to as the "perpendicular septum orientation") is a material limitation in the sense of § 135(b).

In order to demonstrate claim 19 and its dependent claims 20-37 are unpatentable to Twardowski under § 135(b), Martin must show that the claimed perpendicular septum orientation is (a) a material limitation and (b) not expressly or inherently present in the Twardowski claims that were pending prior to the Martin

patent's first anniversary date.[22] See In re Berger, 279 F.3d 975, 981-82, 61 USPQ2d 1523, 1527 (Fed. Cir. 2002):[23]

> To establish entitlement to the earlier effective date of existing claims for purposes of the one-year bar of 35 U.S.C. § 135(b), a party must show that the later filed claim does not differ from an earlier claim in any "material limitation." Corbett v. Chisholm, 568 F.2d 759, 765-66, 196 USPQ 337, 343 (CCPA 1977).
>
> . . . If all material limitations of the copied claim are present in, or necessarily result from, the limitations of the prior claims, then the copied claim is entitled to the earlier effective filing date of those prior claims for purposes of satisfying 35 U.S.C. §135(b). See Corbett, 568 F.2d at 765-66, 196 USPQ at 342; In re Schutte, 244 F.2d 323, 326, 113 USPQ 537, 540(CCPA 1957).

For the following reasons, Martin has failed to demonstrate the materiality of the perpendicular septum orientation.

In contrast to Berger, which observed that "[i]nclusion of a limitation in a claim to avoid the prior art provides strong evidence of the materiality of the included limitation," 279 F.3d

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[22] Twardowski's independent claim 38, which does not recite a septum, is not asserted to be unpatentable under 35 U.S.C. § 135(b).

[23] Berger specifically rejected the argument that compliance with the "same or substantially the same invention" requirement of 35 U.S.C. § 135(b) can be judged in accordance with the "same patentable invention" standard of 37 CFR § 1.601(n), which involves comparing claims to each other to determine whether the subject matter of one claim is anticipated by or would have been obvious from the subject matter of another claim. 279 F.3d at 981-82, 61 USPQ2d at 1527.

at 982, 61 USPQ2d at 1527-28, and thus agreed with the Board that the limitation in question was material because it had been added to overcome a rejection based on prior art, id., the perpendicular septum orientation at issue here was present in Martin's originally filed claims 1 and 16, the only originally filed independent claims.[24] Moreover, as these claims were never rejected for unpatentability over prior art or on any other ground, Martin never argued that the perpendicular septum orientation distinguishes the claims from the prior art. Nor does the record show that the examiner made such a determination in deciding to allow the application. Instead, the examiner's "Statement of Reasons for Allowance" (Paper No. 10, at 3) specifically relies on only the claimed precurvature of the catheter to distinguish claim 1 from the prior art:

> The following is an Examiner's Statement of Reasons for Allowance: the recitation in the claims, inter alia, of the limitation that the proximal and distal portions are linked by a permanently curved portion such that the curved, distal and proximal portions lie naturally in essentially the same plane with the angle contained between the proximal and distal portions being less than 90°, was neither found nor suggested in the prior art of record.

In our view, the examiner's use of the term "inter alia" in the foregoing passage is too vague to be understood as implying that

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[24] Original claim 16 and its dependent claims 17 and 18 were canceled as drawn to a non-elected invention.

the decision to allow the claim over the prior art was additionally based on another claimed feature, let alone on the recited perpendicular septum orientation.

Martin's other arguments for materiality are likewise unpersuasive. The first is that "Figures 2, 3, 4, 6 and 7 of the [involved Martin] '592 patent all show the catheter septum oriented perpendicular to the plane defined by the bend" (MBr. 48, ¶ 71). Inasmuch as all of these figures represent the sole embodiment depicted in the drawings, Martin's position appears to be that every feature in a sole disclosed embodiment is necessarily material. Martin cites no authority in support of such a proposition and we are aware of none.

The next argument is that the materiality of the perpendicular septum orientation is evident from the advantages described in the following passage at column 5, lines 7-22 of the '592 patent:

> [1] Because the septum lies at right angles to the general plane containing the [catheter] body, movement of the proximal and distal portions 26, 30 away from one another or towards one another can be accommodated in the material in the curved portion 28 because the septum lies along a plane of minimal stress, on the neutral axis of the extension. [2] Also the septum tends to help with the integrity of the structure because any tendency to flatten the curved portion by applying load on the outer extremities of the septum will be resisted by the septum. [3] Similarly, if a

> load is applied at right angles to the septum, this will tend to make the tubing oval and this is resisted by the septum which is then in tension.
> [4] Consequently the septum tends to aid in resisting forces applied to deform and flatten the tube.

The ability of the septum to resist forces applied to the catheter wall either parallel to the plane of the septum (sentence 2) or perpendicular thereto (sentence 3) is independent of the orientation of the septum with respect to the plane of the curvature of the catheter. As a result, the advantages recited in those sentences and sentence 4 are not attributable to the claimed perpendicular septum orientation. Thus, only the advantage recited in sentence 1 is attributable to the claimed perpendicular septum orientation, an advantage which the APJ, with Martin's apparent approval (MBr. 92), paraphrased to mean that "the perpendicular orientation of the septum relative to the plane of the precurved catheter . . . allows easier flexing in that plane than would a septum that is parallel to that plane" (Motions Decisions at 26).

In our opinion, rather than serving as evidence of the materiality of the perpendicular septum orientation, sentence 1 simply recognizes that a flexible catheter having a diametric septum, such as the Martin '252 straight catheter mentioned in Martin's involved patent, inherently will bend most easily in the plane which is perpendicular to the plane of the septum. Martin

has not argued, let alone demonstrated, that one skilled in the art would have failed to recognize this inherent property of the Martin '252 catheter. Cf. Reiser v. Williams, 255 F.2d 419, 421, 118 USPQ 96, 98 (CCPA 1958)("Whether a motor is mounted rigidly with or separately from the device or gearing which it drives is a matter of choice well within the province of a skilled mechanic"); id. at 421, 118 USPQ at 99 ("The exact location of the axis of the power takeoff with respect to the support is a matter of design and convenience and it would have been an obvious expedient to make the two coaxial"); id. at 422, 118 USPQ at 99 ("the differences between the counts and claim 6 of Williams involve mechanical expedients only"); and Stalego v. Heymes, 263 F.2d 334, 339, 120 USPQ 473, 478 (CCPA 1959) ("Whether the material is heated to molten condition in or out of the combustion chamber is obviously a matter of design choice."). We note that in testifying that they never contemplated using any other septum orientation, inventors Martin and Last (Martin Decl. MX D, ¶ 14, Last Decl. MX E, ¶ 11) did not deny that one skilled in the art would have been aware of this inherent property of a flexible catheter having a diametric septum. Nor is such a denial offered in support of the assertions of materiality given by technical expert Dr. Quinton (Quinton Decl. MX F, ¶ 22) and

patent expert Robert Mallinckrodt (Mallinckrodt Decl. MX M, ¶¶ 12-20).

The fact that the perpendicular septum orientation is recited in the claims of foreign counterpart applications (MX C and MX G through L) likewise fails to show materiality. To the contrary, it may simply reflect an awareness that a flexible catheter having a diametric septum inherently will bend most easily in the plane perpendicular to the plane of the septum.

For the foregoing reasons, the APJ's decision denying Martin's Motion A for failing to demonstrate the materiality of the perpendicular septum orientation was therefore correct. In view of Martin's failure to show materiality, which is the first step of the Berger § 135(b) analysis, we do not reach the second step, which is to determine whether the perpendicular septum orientation "is present in, or necessarily result[s] from, the limitations of the prior claims." Berger, 279 F.3d at 982, 61 USPQ2d at 1527 (citing Corbett, 568 F.2d at 765-66, 196 USPQ at 342; Schutte, 244 F.2d at 326, 113 USPQ at 540)).

(c) Whether Twardowski's claims are unpatentable over Martin's '122 Canadian patent and other grounds newly asserted in Martin's opening brief

During the preliminary motion period, Martin filed a single motion alleging unpatentability of Twardowski's claims over prior art. That motion is Martin's Motion B, which argues that

Twardowski's claims 1 and 38 are unpatentable under 35 U.S.C. § 103 over Martin Patent 5,053,023 (MX T)(hereinafter "Martin '023"), Twardowski et al. Patent 4,687,471 (MX P)("Twardowski '471"), and Schon et al. Patent 4,981,477 (MX R). The APJ denied this motion on the merits. Motions Decisions at 41-47. Martin has not requested review of the denial of that motion at final hearing.

Instead, following the close of the preliminary motion period, Martin filed a motion entitled "Motion of Junior Party Martin to Consider Newly Discovered Prior art,"[25] which was accompanied by a copy of Canadian Patent 1,150,122 (MX 2) ("Martin '122") to Geoffrey Martin, one of the two named inventors in the involved Martin patent. That motion, which indicates it is filed "[p]ursuant to 37 C.F.R. § 1.621 et seq." (Motion at 1), asserts that Twardowski's claims 1 and 38 are anticipated by the Martin '122 patent and that claim 19 "may also be impacted" by that patent (Motion at 3-4). The motion further explains:

> Martin feels obligated to bring this newly discovered and very relevant prior art to the attention of the APJ, and pursuant to the APJ's authority under 37 CFR § 1.641 requests that the APJ consider this prior art's impact on validity of the claims corresponding to the count. It clearly is in the

[25] Paper No. 136.

> interest of justice and the public interest to consider highly relevant prior art before proceeding further. If the APJ desires further briefing pursuant to § 1.641, Martin is prepared to respond as requested.

Motion at 4. ***

The motion's citation of "§ 1.621 et seq." as the basis therefor is not understood, as §§ 1.621 through 1.629 all relate to the content and effect of the parties' preliminary statements. However, in accordance the motion's request that the APJ exercise his authority under § 1.641 and the fact that Martin's opening brief contends (at 72) that the motion "was brought pursuant to Section 1.641 (not Section 1.633) and thus was a 'miscellaneous motion' not subject to the same limitations applicable to preliminary motions. 37 C.F.R. 1.635, 1.636," we are treating it as a miscellaneous motion under § 1.635[26] requesting the APJ to exercise his discretionary authority under § 1.641.[27] For the reasons addressed below, the APJ dismissed this § 1.635 motion/§ 1.641 request (hereinafter "§ 1.641

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[26] Section 1.635 reads:

> § 1.635 Miscellaneous motions.
>
> A party seeking entry of an order relating to any matter other than a matter which may be raised under §§ 1.633 or 1.634 may file a motion requesting entry of the order. See § 1.637 (a) and (b).

[27] It is the Board's policy to treat interference papers in accordance with their contents rather than their captions. Pfluger v. Wertheim, 203 USPQ 874, 877 (Comm'r Pats. & Trademarks 1978).

request") in a paper entitled "Decision dismissing Martin's motion to consider Canadian Patent No. 1,150,122" (hereinafter "Decision dismissing § 1.641 request").[28]

Martin's opening brief challenges the APJ's dismissal of the § 1.641 request, argues the merits of the grounds for unpatentability stated in the request, and argues the following three new grounds for unpatentability: (a) that Twardowski's claim 1 is unpatentable under 35 U.S.C. § 103 for obviousness over Martin '122 in view of Twardowski '471; (b) that Twardowski's claims 19-38 are unpatentable under 35 U.S.C. § 103 for obviousness over Martin '122, Martin '023, and Twardowski '471; and (c) that Twardowski's claim 1 is unpatentable under 35 U.S.C. § 102(b) based on prior sales and public uses of the Vas-Cath SC-400 catheter in the United States. MBr. 64-80.

The APJ's dismissal of the § 1.641 request will be addressed first. First, the APJ noted (Decision dismissing § 1.641 request, at 1-2) that the filing of a § 1.641 request is specifically prohibited by the following instruction, which appears at page 23 of the APJ's "Guidelines"[29] governing this interference:

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[28] Paper No. 142.

[29] Declaration notice, Interference Paper No. 2, at 2-25.

> Requests for the undersigned to exercise discretion
>
> . . . .
>
> It is inappropriate to use a request under § 1.641 as a substitute for a proper motion[30] under § 1.633(a). Compare Jacobs v. Moriarity, 6 USPQ2d 1799, 1802 (Bd. Pat. App. & Int. 1988), in which the Board, after holding that Moriarity's § 1.633(a) motion had been [properly] dismissed by the APJ, rejected Moriarity's alternative argument that the unpatentability issue raised in the motion should be considered by the APJ and the Board pursuant to their authority under § 1.641:
>
> > [Section] 1.641 is clearly discretionary with the EIC [now APJ]. He obviously elected not to exercise that discretion; nor do we here. Reference to that section cannot be used to thwart the purpose of the rules which place the burden of establishing unpatentability in a preliminary motion on movant. See Theeuwes v. Bogentoft, 2 USPQ2d 1378 (Comm'r 1987).

In addition, the APJ alternatively treated the § 1.641 request as a belated motion under § 1.633(a), which he then dismissed on the ground that Martin failed to show "good cause" for the belatedness, as required by the following part of 37 CFR § 1.645(b):

> (b) Any paper belatedly filed will not be considered except upon motion (§ 1.635) which shows good cause why the paper was not timely filed, or where an administrative patent judge or the Board, sua

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[30] A "proper" motion is a motion that is either timely filed or belatedly filed with a satisfactory showing of good cause for the belatedness. Cf. English v. Ausnit, 18 USPQ2d 1625, 1640 (Bd. Pat. App. & Int. 1994)("A 37 CFR 1.633(a) motion is "properly filed" [under § 1.655(b)] if it is filed either during the preliminary motion period or after expiration of the preliminary motion period, provided it is accompanied by a 37 CFR 1.645(b) showing of "sufficient cause" for the belatedness.").

> sponte, is of the opinion that it would be in the interest of justice to consider the paper.

The "good cause" alleged in the § 1.641 request was the discovery of the Canadian '122 during a reinvestigation of evidence relating to conception and diligence following the APJ's January 8, 2001, redeclaration of the interference to replace Count 1 with Count 2 and invitation for the parties to submit new preliminary statements directed to Count 2 (Motions Decisions at 55). The APJ rejected this argument on the grounds that patentability questions concern claims rather than counts, In re Van Geuns, 988 F.2d 1181, 1184, 26 USPQ2d 1057, 1059 (Fed. Cir. 1993), and that the Twardowski claims which are the subject of the belated motion have been involved in the interference ever since it was initially declared.[31] Martin does not challenge

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[31] As support for the conclusion that these circumstances do not constitute § 1.645(b) good cause, the APJ's Decision dismissing § 1.641 request states, at 2-4:

> As explained in Maier v. Hanawa, 26 USPQ2d 1606, 1610 (Comm'r Pats. 1992), discussing a belated motion under § 1.633(c)(3) to add claims to the interference:
>
> > [I]t is incumbent on a party to make its best reasonable effort within the time period allotted by the EIC to uncover all evidence on which it would rely in making a preliminary motion. If information which could have been discovered with reasonable effort within the period set by the EIC, its later discovery after the expiration of the period would not be sufficient cause for delay in the late filing of any preliminary motion

(continued...)

this holding by the APJ.[32] Nor does Martin take issue with the APJ's rejection of the alternative excuse, offered during an

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[31](....continued)
relying on that information. [Footnote omitted.] [26 USPQ at 1610.]
See also Suh v. Hoefle, 23 USPQ2d 1321, 1324-25 (Bd. Pat. App. & Int. 1991)("Prior to the expiration of the preliminary motions period, Suh had available to him experts, such as the Suh inventors, who knew of, or could have been made aware of, both the Merck public disclosure and the prior art patents. Thus, Suh was in possession of the necessary evidence to enable him to prepare affidavit(s) setting forth those matters . . . which are now being relied upon by Suh to show unpatentability [footnote omitted]. By being in possession of this evidence, Suh had no legitimate reason for not presenting it in a timely filed motion. Cf. Hanagan v. Kimura, 16 USPQ2d 1791 (Comm'r. Pat. 1990); Orikasa v. Oonishi, 10 USPQ2d 1996, note 4 (Comm'r. Pat. 1989)."). Cf. General Instrument Corp. v. Scientific-Atlanta Inc., 995 F.2d 209, 213, 27 USPQ2d 1145, 1148 (Fed. Cir. 1993)("Upon receipt of Scientific-Atlanta's preliminary statement and first information disclosure statement in June 1988, General Instrument could not have made a preliminary motion for judgment on the public use issue because the March 1987 deadline for such motions was long past. General Instrument, however, could have filed a belated preliminary motion for judgment on that ground, but it did not do so. Such a motion likely would have met the good cause requirement the PTO imposes on belated motions because the information underlying the motion, Scientific-Atlanta's preliminary statement and disclosure statement, had not been available earlier in the proceeding. See 37 C.F.R. §§ 1.640(b), 1.645(b), 1.655(b)(1992).").
(Brackets in original.)

[32] The only one of the foregoing decisions mentioned in Martin's opening brief is Orikasa, which it cites for a principle unrelated to the "good cause" requirement of § 1.645(b) (MBr. 51).

April 17, 2001, conference call, that Martin's current patent counsel did not begin to represent Martin until after the close of the preliminary motion period.[33]

Instead, Martin argues that in view of "the long-recognized public interest in ensuring that only deserving patents issue" (MBr. 71), the APJ abused his discretion[34] by failing to consider the merits of the patentability issue either (a) pursuant to his authority under § 1.641, which permits an APJ to consider a

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[33] Specifically, the APJ held:

> It is well settled that a delay in bringing a motion will not be excused if, as in this case, it appears that the lateness of the motion was due to a change in opinion or purpose arising from a change of attorneys. See 2 C. Rivise & A. Caesar, Interference Law and Practice, § 270 at 1091 (Michie Co. 1943). See also Suh v. Hoefle, 23 USPQ2d 1321, 1324 (Bd. Pat. App. & Int. 1991)("In our view, Suh was aware of, or should have been aware of, the prior art patents, the interference estoppel argument and the public disclosure at the time preliminary motions were due. Thus, it appears that this belated preliminary motion was filed because of a change of opinion or purpose, which does not constitute good cause for excusing the belatedness of a motion.")(citing Interference Law and Practice § 270).

Decision dismissing § 1.641 request, at 5.

[34] An abuse of discretion occurs if a decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision. Abrutyn v. Giovanniello, 15 F.3d 1048, 1050-51, 29 USPQ2d 1615, 1617 (Fed. Cir. 1994) (citing Heat & Control, Inc. v. Hester Indus. Inc., 785 F.2d 1017, 1022, 228 USPQ 926, 930 (Fed. Cir. 1986)).

patentability issue raised "at any time during an interference," or (b) when the § 1.641 request is treated as a belated § 1.633(a) motion, pursuant to the "interest of justice" provision of § 1.645(b), which Martin notes permits consideration of a belatedly filed paper even in the absence of a showing of good cause for the delay. Alternatively, Martin requests that we consider this patentability issue and the others raised in the brief pursuant to the Board's discretionary authority under § 1.655(c), reproduced infra.

We will begin with Martin's § 1.641 argument, which we understand to be that the APJ abused his discretion by issuing a guideline provision specifically prohibiting the parties from filing § 1.641 requests in lieu of timely or belated § 1.633(a) motions. Not only does this guideline provision find clear support in Jacobs, 6 USPQ2d at 1802, which is quoted in that provision, it is consistent with the language of § 1.641(a), which in using the term "sua sponte" and authorizing the APJ to enter an order notifying the parties of the reasoning and requesting their views makes it clear that § 1.641 is limited to patentability issues raised by the APJ without prompting by a party:

> (a) During the pendency of an interference, if the administrative patent judge becomes aware of a reason why a claim designated to correspond

> to a count may not be patentable, the administrative patent judge may enter an order notifying the parties of the reason and set a time within which each party may present its views, including any argument and any supporting evidence, and, in the case of the party whose claim may be unpatentable, any appropriate preliminary motions under §§ 1.633(c), (d) and (h).

(Emphasis added.) See also In re Roemer, 258 F.3d 1303, 1307, 59 USPQ2d 1527, 1529 (Fed. Cir. 2001)(describing § 1.641 as "allowing an administrative patent judge to raise the issue of patentability sua sponte as to claims designated to correspond to a count"); General Instrument 995 F.2d at 212, 27 USPQ2d at 1147 ("The Board may consider any properly raised issue which, in addition to issues raised in preliminary motions, may include issues of unpatentability presented by the examiner-in-chief [under § 1.641]."); and Rowe v. Dror, 112 F.3d 473, 477, 42 USPQ2d 1550, 1552 (Fed. Cir. 1997):

> The PTO may, during the course of an interference, determine the patentability of any claim involved in the interference. See 37 CFR § 1.633(a)(1996)(allows a party to an interference to move for judgment against the other party on the grounds that the count is not patentable to that party for any reason other than priority or derivation); see also 37 CFR § 1.641 (1996)(allows administrative patent judge to raise the issue of patentability sua sponte)."

The foregoing interpretation of § 1.641 is consistent with the absence of any authority holding that an APJ's failure to consider the merits of a § 1.641 request is entitled to review by

the Board or that the Board's affirmance of an APJ's refusal to consider the merits of such a request is subject to court review. In In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000), the Federal Circuit held that the Board's affirmance of an APJ's sua sponte decision to exercise his discretion under § 1.641 to hold claims unpatentable over prior art is reviewable for an abuse of discretion; the Court did not address the question of whether an APJ's failure to exercise § 1.641 discretion is subject to Board review or the question of whether a Board decision affirming such inaction by an APJ would be subject to court review.

Assuming for the sake of argument that a party is entitled to Board and court review of an APJ's failure to consider the merits of a § 1.641 request, we are not persuaded that the APJ's refusal to consider the merits of Martin's § 1.641 request constitutes an abuse of discretion. While, as Martin correctly notes, there is a public interest in ensuring the validity of patents, that interest does not trump the need for a patentability issue known to a party to be raised in the manner specifically set forth in the rules, namely, in a timely or belated preliminary motion under § 1.633(a). See Myers v. Feigelman, 455 F.2d 596, 601, 172 USPQ 580, 584 (CCPA 1972)("the [interference] rules are designed to provide an orderly procedure

and the parties are entitled to rely on their being followed in the absence of such circumstances as might justify waiving them under Rule 183.").[35] One aspect of this "orderly procedure" is that motions under § 1.633(a) alleging unpatentability must satisfy the burden of proof requirements of § 1.637(a)[36] and the decisions addressing a movant's burden under § 1.633(a), including Chiong v. Roland, 17 USPQ2d 1541 (Bd. Pat. App. & Int. 1990), which held:

> The motion [under § 1.633(a)] is dismissed for failure to comply with 37 CFR 1.637(a)(2) and (3).
> . . .
> As the proponent of the proposition that Chiong's claim 28 is unpatentable, Roland has the burden to clearly establish such. Jacobs v. Moriarity, 6 USPQ2d 1799 ([Bd. Pat. App. & Int.] 1988). As pointed out by

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[35] Section 1.183 reads as follows:
§ 1.183 Suspension of rules.
In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Commissioner or the Commissioner's designee, sua sponte, or on petition of the interested party, subject to such other requirements as may be imposed. Any petition under this section must be accompanied by the petition fee set forth in § 1.17(h).

[36] Section 1.637(a) reads in pertinent part:
(a) A party filing a motion has the burden of proof to show that it is entitled to the relief sought in the motion. Each motion shall include a statement of the precise relief requested, a statement of the material facts in support of the motion, in numbered paragraphs, and a full statement of the reasons why the relief requested should be granted.

> the Board in Jacobs, the burden on the movant is no less than on an Examiner making a rejection of claims or on a Requestor for reexamination. See MPEP 706 and 2214. Certainly, if Roland considered any of the references to be anticipatory, he should have pointed to the disclosure in the reference - by page and line - upon which claim 28 reads. He did not. Similarly, if Roland considered the subject matter of claim 28 to have been obvious, he should have analyzed the references in accordance with the MPEP and with the principles of Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). He did not. In other words, Roland did not make out a prima facie case for obviousness as he is required to do.

17 USPQ2d at 1543. Martin's reliance on § 1.641 rather than § 1.633(a) also deprived Twardowski of a clear right to respond to the patentability challenge with a responsive motion under § 1.633(c), (d), or (h), as a party whose claims are the target of a § 1.633(a) motion is authorized to do by § 1.633(i).[37]

The foregoing procedural deficiencies also mean that the patentability issues were not "fairly and fully developed," as required for their consideration by the APJ and the Board. See Berman v. Housey, 291 F.3d 1345, 1352, 63 USPQ2d 1023, 1028 (Fed. Cir. 2002):

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[37] Section 1.633(i) reads:

> (i) When a motion is filed under paragraph (a), (b), or (g) of this section, an opponent, in addition to opposing the motion, may file a motion to redefine the interfering subject matter under paragraph (c) of this section, a motion to substitute a different application under paragraph (d) of this section, or a motion to add a reissue application to the interference under paragraph (h) of this section.

> Perkins v. Kwon, 886 F.2d 325, 12 USPQ2d 1308 (Fed. Cir. 1989); Guinn v. Kopf, 96 F.3d 1419, 40 USPQ2d 1157 (Fed. Cir. 1996); Wu v. Wang, 129 F.3d 1237, 44 USPQ2d 1641 (Fed. Cir. 1997); Schulze v. Green, 136 F.3d 786, 45 USPQ2d 1770 (Fed. Cir. 1998); and In re Gartside, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000) . . . stand for the proposition that if, in a properly declared interference, an issue of priority or patentability is fairly raised and fully developed on the record, then the Board has the authority to consider that issue even after the Board determines that one party was not entitled to its claims.

Turning now to Martin's the § 1.645(b) "interest of justice" argument, Martin argues that the APJ, when treating the § 1.641 request as a belated § 1.633(a) motion, should have exercised his sua sponte "interest of justice" authority under § 1.645(b) to consider the merits of the unpatentability charge despite his conclusion that § 1.645(b) "good cause" has not been shown. This argument is entitled to no consideration because the exercise of "interest of justice" authority was not requested in Martin's § 1.641 request. Cf. Bayles, 16 USPQ2d at 1391 ("It has been a long standing practice that a party whose motion was denied cannot present at final hearing reasons in favor of granting the motion if those reasons were not included in the original motion." In any event, § 1.645(b)'s description of the "interest of justice" authority as "sua sponte" authority clearly excludes grounds argued by a party, which therefore must be judged in accordance with § 1.645(b)'s "good cause" provision.

Finally, even assuming a party is entitled to request the exercise of § 1.645(b) "interest of justice" authority, for the reasons given above we are not persuaded that an APJ's failure to consider or grant a request for the exercise of such sua sponte authority is subject to review by the Board or that a Board decision affirming such treatment by the APJ is subject to court review.

That brings us to Martin's request that we consider the patentability issues raised in the § 1.641 request and also the patentability issues raised for the first time in Martin's opening brief pursuant to our discretion under § 1.655(c), which specifies that "[i]n the interest of justice, the Board may exercise its discretion to consider an issue even though it would not otherwise be entitled to consideration under this section." In support of the exercise of such authority, Martin again cites the general public interest in ensuring the validity of patents. For the reasons given above, this public interest does not override the need for an orderly interference procedure, which as explained above requires that patentability issues be raised in timely or belated motions under § 1.633(a) rather than in § 1.641 requests. As noted above in the discussion of Martin's reliance on priority evidence as support for the § 1.633(a) motion alleging unpatentability under 35 U.S.C. § 112, this procedure

also precludes Martin from presenting patentability issues for the first time in a brief. See Interference Practice: Matters Relating to Belated Preliminary Motions, 1144 Off. Gaz. Pat. Office 8, 8 (Nov. 3, 1992)(where evidence that provides a basis for a motion under 37 CFR 1.633(a) does not come to light until after the end of the preliminary motion period, the board will not consider the matter unless the party, promptly after the evidence becomes available, files a belated preliminary motion under § 1.633(a) and a motion under § 1.635 showing sufficient cause[38] under § 1.645(b) for the belatedness).

Finally, we note that the Board's refusal to consider a belatedly raised patentability issue pursuant to its discretionary authority under § 1.655(c) was affirmed in Credle v. Bond, 25 F.3d 1566, 1572 n.14, 30 USPQ2d 1911, 1916 n.14 (Fed. Cir. 1994):

> The Board held . . . that any challenge under 35 U.S.C. § 112 ¶ 1 to the basis of the count's "swing into the liquid" limitation was untimely, because the issue could have been raised in a preliminary motion, but was not. § 1.655(b); see Heymes v. Takaya, 6 USPQ2d 1448, 1452 (Bd. Pat. App. & Interf. 1988). Since Credle has failed to argue that his failure to raise the issue was

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[38] Effective April 21, 1995, the term "sufficient cause" in § 1.645(b) was changed to "good cause" to be consistent with the terminology used in other interference rules. Patent Appeal and Interference Practice -- Final Rule, 60 Fed. Reg. 14,488, 14,513 (March 17, 1995); 1173 Off. Gaz. Pat. & Trademark Office 36, 57 (April 11, 1995).

> for "good cause," the Board did not abuse its discretion in not considering the issue. See § 1.655(b), (c) (Board may consider untimely raised issue "[t]o prevent manifest injustice."); Conservolite, Inc. v. Widmayer, [21] F.3d [1098, 1101-02], 30 USPQ2d 1626, [1628-30] (Fed. Cir. 1994) (& cases cited therein) (discussing consequences of not raising issue in preliminary motion); see also United States Dep't of Energy v. Daugherty, 687 F.2d 438, 446, 215 USPQ 4, 11 (CCPA 1982).

In Daugherty, the issue was whether our predecessor Board of Patent Interferences abused its discretion under § 1.258(a), the predecessor of current § 1.655(c), by refusing to consider non-enablement and best mode issues raised after the preliminary motion period had ended. The court held that it did not:

> Appellants allege that evidence uncovered only after the end of the motion period convinced them of the propriety of raising the § 112 issues. The new evidence on the enablement question was the opinion of Daugherty's final expert witness that the count conditions were not satisfied by Daugherty's sole disclosed working example. Appellants, however, presumably had access to experts of their own, not to mention the evident experience of applicants themselves. Thus, there was no reason why appellants themselves could not have discovered the alleged defect in the Daugherty specification. Under these circumstances, the board did not abuse its discretion when it declined to take up the enablement issue.

687 F.2d at 446, 215 USPQ at 11. Also, in Larson v. Johenning, 17 USPQ2d 1610, 1615 (Bd. Pat. App. & Int. 1990), the Board denied a request to exercise its discretion under § 1.655(c) to consider a belated motion attacking benefit, citing Myers, which as noted above held that the interference rules are designed to

provide an orderly procedure and the parties are entitled to rely on their being followed in the absence of such circumstances as might justify waiving them under § 1.183. Myers, 455 F.2d at 601, 172 USPQ at 584.

For the foregoing reasons, we decline to exercise our discretionary authority under § 1.655(c) to consider whether Twardowski's claims are unpatentable (a) over the Martin '122 Canadian patent considered alone or in combination with other prior art, as asserted in the § 1.641 request, or (b) on any of the other grounds argued for the first time in Martin's opening brief.

(d) Summary of effect of Martin's allegations of unpatentability

In summary, we are not entering judgment against any of Twardowski's claims for unpatentability on any of the grounds urged by Martin or on any other ground.

E. MARTIN'S PRIORITY CASE

Martin's case for priority is restricted to Alternative A of Count 2, the alternative which is identical to Twardowski's claim 1 and thus recites the "generally U-shape" requirement. Count 2 reads as follows:[39]

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[39] Alternative B is identical to Martin's claim 1 and Alternative C is identical to Twardowski's claim 38.

Count 2

A. A catheter for hemodialysis which comprises a flexible catheter tube defining a plurality of separate lumens, said catheter defining an arc angle of generally U-shape in its natural, unstressed configuration, whereby said catheter may be implanted with a distal catheter portion residing in a vein of a patient, said distal catheter portion being of substantially the shape of said vein in its natural, unstressed condition, and a proximal catheter portion residing in a surgically created tunnel extending from said vein and through the skin of the patient, whereby blood may be removed from said vein through one lumen of the catheter and blood may be returned to said vein through another lumen of the catheter;

or

B. A flexible catheter for prolonged vascular access, the catheter comprising: an elongate flexible and tubular body having a proximal portion, a distal portion and a permanently curved portion linking the proximal and distal portions so that the curved, the proximal and the distal portions lie naturally in essentially the same plane with the angle contained between the proximal and distal portions being less than 90°, and a septum extending continuously through said portions and lying substantially at right angles to said plane to divide the tubular body into generally D-shaped intake and outlet lumens; intake and outlet tubes coupled to the proximal portion at a proximal end of the body remote from the curved portion to receive incoming fluid from the intake lumen and to supply outgoing fluid to the outlet lumen; and a tip formed on the distal end of the distal portion and including at least one intake opening for receiving the incoming fluid and at least one outlet opening for returning the outgoing fluid;

or

C. A flexible catheter for prolonged vascular access, the catheter comprising: an elongate flexible and tubular body having a proximal portion, a distal

> portion and a permanently curved portion linking the proximal and distal portions so that the curved, the proximal and the distal portions lie naturally in essentially the same plane with the angle contained between the proximal and distal portions being less than 90°; intake and outlet tubes coupled to the proximal portion at a proximal end of the body remote from the curved portion to receive incoming fluid from the intake lumen and to supply outgoing fluid to the outlet lumen; and a tip formed on the distal end of the distal portion and including at least one intake opening for receiving the incoming fluid and at least one outlet opening for returning the outgoing fluid.

(Emphasis added.) Martin argues that the evidence shows:

(1) a constructive reduction to practice in the United States of the Alternative A subject matter on April 13, 1981, when the Martin U.S. Application 06/254,019 (MX 1)(hereinafter "the '019 application") was filed, naming only Geoffrey Martin as an inventor and claiming benefit of the Martin '122 Canadian patent (MBr. 22-25, ¶¶ 18-23; MBr. 51-54); and

(2) an actual reduction to practice in the United States of the Alternative A subject matter when units of the Vas-Cath SC-400 catheter were sold and distributed in the United States (MBr. 25-26, ¶¶ 24-26; MBr. 54-55). The dates of these alleged acts are not given in Martin's opening brief. However, inventor Geoffrey Martin testified that U.S. distribution and sales of SC-400 catheters began on May 8, 1980. Martin Decl. B, ¶ 6 (MR 16).

Martin does not alternatively argue either (a) prior conception coupled with diligence or (b) derivation by Twardowski.

All of the alleged reductions to practice fail for several reasons, chief of which is their failure to satisfy the "generally U-shape" requirement of Alternative A.

The matter of count interpretation was addressed as follows in Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 42 USPQ2d 1608 (Fed. Cir. 1997):

> [P]roper construction of the count . . . is a question of law. DeGeorge v. Bernier, 768 F.2d 1318, 1321, 226 USPQ 758, 760 (Fed. Cir. 1985). To construe the count we must look at the language as a whole and consider the grammatical structure and syntax. Credle v. Bond, 25 F.3d 1566, 1571, 30 USPQ2d 1911, 1915 (Fed. Cir. 1994).
>
> > In the absence of ambiguity, it is fundamental that the language of a count should be given the broadest reasonable interpretation it will support and should not be given a contrived, artificial, or narrow interpretation which fails to apply the language of the count in its most obvious sense. Only when counts are ambiguous may resort be had to the application where the counts originated, and this court does not look to the specification to determine whether there is an ambiguity.
>
> In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 802 (CCPA 1981) (citations omitted).

Genentech, 112 F.3d at 500, 42 USPQ2d at 1612. The term "generally U-shape" as used in Alternative A of Count 2 is unambiguous and has the same meaning as does "generally U-shape"

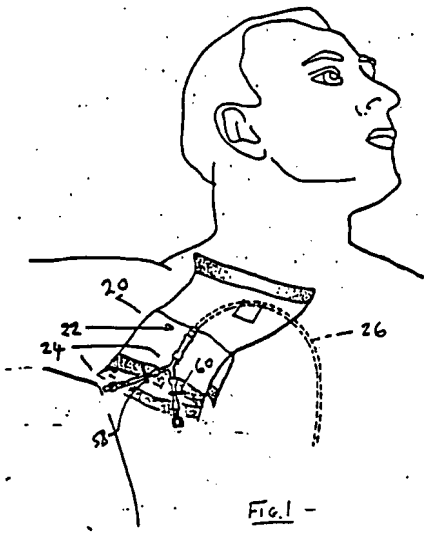
in Twardowski's claim 1: it refers to a shape consisting of a pair of laterally spaced, at least approximately parallel leg portions having their respective first ends joined together by a connecting portion, which may be curved or straight. The requirement that the leg portions be at least approximately parallel can also be described as a requirement that the leg portions point in at least approximately the same direction. Furthermore, the count language is broad enough to read on a catheter that is generally U-shaped either in whole or in part.[40]

(a) Whether the catheter disclosed in the '019 application satisfies the requirements of Count 2, Alternative A

Although the '019 application describes the outer lumen 26 as being "pre-formed to have an arcuate curve reflecting the general shape of the subclavian vein" (Specification at 4, ll. 23-25), it does not indicate that the amount of this preformed curvature is accurately depicted in either Figure 1 or Figure 2. Figure 1 (reproduced below) shows the cannula 22 after insertion into a patent's vein and after being secured in place by means of

[40] As is the case with Twardowski's claim 1, we understand the phrase "said catheter defining an arc angle of generally U-shape" to mean the catheter defines an arc angle which results in a catheter of generally U-shape.

a conventional adhesive dressing 20 (id. at 5, l. 24 to p. 6, l. 1):



That this figure cannot be assumed to accurately depict the shape of the cannula (i.e., catheter) in its unstressed condition is evident from the fact that the same figure (with different reference numerals) is employed as Figure 6 in each of the following two documents to represent an in-use catheter which is not described as being preformed with any curvature: (1) the alleged joint application by Geoffrey Martin and Peter Uldall (MX 3; MBr. 17-18, ¶ 10); and (2) Uldall's Canadian Patent 1,092,927 (MX 4). Figure 6 in each of those two documents is as follows:

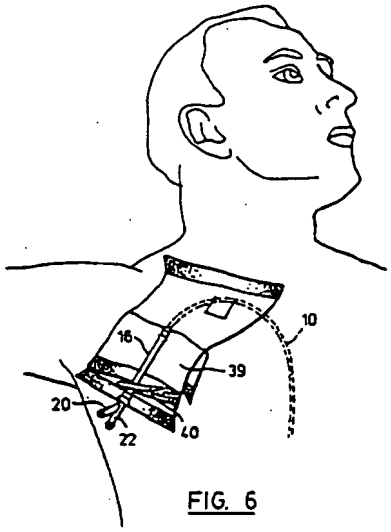
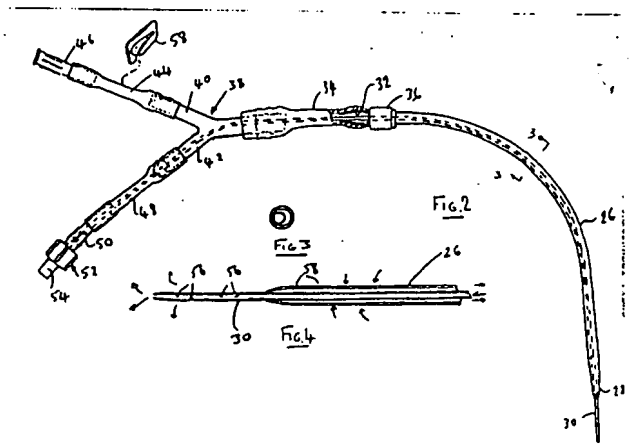


FIG. 6

Although Figure 2 (reproduced below) of the '019 application shows a catheter which is not implanted in a patient, the specification does not indicate that this figure accurately depicts the shape of the precurved catheter in its unstressed condition:



Absent such a description in the specification, this figure cannot be assumed to accurately depict the amount of precurvature of the catheter. Hockerson-Halberstadt, 222 F.3d at 956, 55 USPQ2d at 1491. Thus, the failure of the '019 specification to describe Figure 2 as showing the amount of precurvature leaves open the possibility that the figure shows the extent to which the catheter can be bent beyond its precurved configuration without kinking. This conclusion finds support in the fact that the catheter disclosed in Uldall Canadian Patent 1,092,927 (MX 4), which is not described as being precurved,[41] is depicted in its unimplanted condition (Figure 1, reproduced below) as having even more curvature than is shown in Figure 2 of the '019 application.

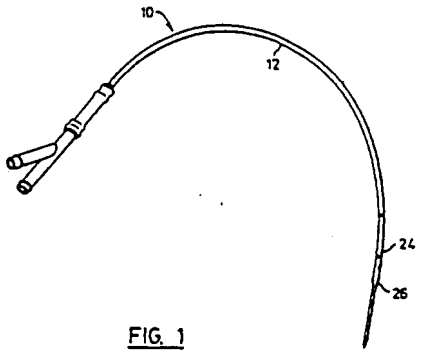


FIG. 1

[41] Instead, the inner and outer lumens are formed of tetrafluoroethylene polymer so as to "hav[e] the necessary degree of flexibility to assume the configuration of the subclavian vein and superior vena cava without kinking or buckling or otherwise constricting the flow of fluid therethrough" (MX 4, at 5, ll. 6-13).

Finally, even assuming for the sake of argument that the amount of precurvature of outer lumen 26 is accurately depicted in Figure 2 of the '019 application, the catheter is not generally U-shaped, as Martin contends (MBr. 22-23, ¶ 20). Instead, the proximal and distal end portions of the outer lumen point in directions which are nearly perpendicular to each other.

For the foregoing reasons, Martin has failed to establish that the '019 catheter satisfies the "generally U-shape" requirement of Alternative A of Count 2, as is necessary if that application is to constitute a constructive reduction to practice of that count alternative.[42]

Nevertheless, we have considered Twardowski's additional argument (TBr. 78-79) that the '019 catheter is not "a flexible catheter tube defining a plurality of separate lumens," as required by Alternative A of Count 2. Twardowski construes the language to mean that a single, integral structure defines the two passages, whereas the SC-400 catheter employs "two separate concentric tubes or lumens where the inner tube or lumen can be removed from the outer tube or lumen" (TBr. 79). In support,

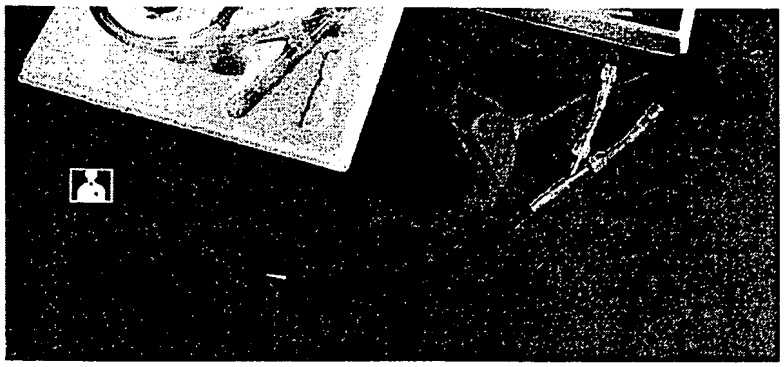
[42] Although not argued by Martin, we note that the "generally U-shape" limitation is not satisfied even if the recited "catheter" is considered to additionally include Y-fitting 38 and extension tubes 44 and 48, because the angle formed between extension tube 48 and the distal end of outer lumen 28 is about 45 degrees, which is too large to satisfy the "generally U-shape" limitation.

Twardowski cites the following definition of "define" from The American Heritage Dictionary of the English Language 364 (3d ed. 1997): "to delineate the outline or form of." TBr. 41, ¶ 99; TBr. 78-79. Because this definition does not require delineating the entire outline or form, we are of the opinion that the count language in question is broad enough to read on using a single tube to delineate at least a portion of the boundary of each of two different lumens as is the case with the '019 catheter, wherein the inner tubular member forms the outer boundary of the inner passage and the inner boundary of the outer passage. In fact, in Twardowski's catheter the tubular member defines only a portion of the outer boundary of both lumens, with the remainder of the outer boundaries being defined by the septum.

(b) Whether the SC-400 catheter alleged to be an actual reduction to practice satisfies the requirements of Count 2, Alternative A

Martin's reliance on the Vas-Cath SC-400 commercial catheter as evidence of an actual reduction to practice of an embodiment satisfying Alternative A of Count 2 is also unpersuasive. The only fact testimony by a witness other than the inventors is by Anand Ram, who was a production supervisor and research and development assistant with Vas-Cath during the period from 1983 to February 1985 (Ram Decl. ¶ 2, MR 31). According to Ram, the Vas-Cath SC-400 catheter that was tested and produced during that

period was a flexible coaxial dual-lumen catheter having an outer lumen which "was pre-curved so that it was generally U-shaped prior to insertion" (id., ¶ 3, MR 31). However, it is evident from his testimony (MR 32, ¶ 4) that the SC-400 model he tested and produced "is embodied by a sheet of drawings entitled 'SC-400 Patent Pending' (. . . Exhibit 6)," reproduced supra at page 19, and from the fact that the end portions of the catheter shown in that exhibit (MX 6) point in nearly perpendicular directions that Ram's interpretation of "generally U-shaped" is unreasonably broad. The same is true of Martin's reliance on an advertisement by Shiley, Inc. for "Shiley's Vas-Cath™ Double Lumen and Single Lumen Subclavian Cannulae," which appears in 12 Dialysis and Transplantation 300 (April 1983) (TX 75), as evidence that generally U-shape SC-400 catheters were offered for sale in the United States in 1983 (MBr. 26, ¶ 25). In the photograph (reproduced below) of the SC-400 catheter in this advertisement, the catheter end portions point in nearly opposite directions.



Like Ram's testimony, the testimony by Martin's expert witness Dr. Quinton to the effect that the SC-400 catheter is an embodiment of the catheter depicted in the '019 application and satisfies all of the limitations of Alternative A of Count 2 (Quinton Decl. ¶ 23, MR 28-29) is based on an unreasonably broad reading of "generally U-shape," as is the similar testimony by inventor Martin (Martin Decl. B ¶ 10, MR 16-17).[43]

We therefore agree with Twardowski that the SC-400 catheter is not generally U-shaped in whole or in part, as is necessary to satisfy Alternative A of Count 2. However, Twardowski's argument (TBr. 78) that the SC-400 catheter does not have "a flexible catheter tube defining a plurality of separate lumens," as required by that count alternative A, is unpersuasive for the reasons given above in the discussion of whether the Martin '019 application constitutes a constructive reduction to practice.

Although Martin's priority evidence fails to demonstrate either a constructive or an actual reduction to practice which satisfies the "general U-shape" requirement of the count, we will also address some of Twardowski's other grounds for attacking Martin's priority case.

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[43] Mr. Last's testimony about the SC-400 catheter (Last Decl. ¶¶ 3-6, MR 21-22) does not characterize it as being generally U-shaped.

(c) Whether Martin should be limited to the dates alleged in Martin's first preliminary statement

Martin's first preliminary statement, which was timely filed during the preliminary motion period, did not mention the Martin '019 U.S. application, the Martin '122 Canadian patent, or any alleged actual reduction to practice in the United States prior to 1989. Instead, that preliminary statement gives May 1, 1989, as the date when a conception was first introduced into the United States and November 9, 1989, as the date on which (a) the invention was first disclosed to another person in the United States, (b) a written description, drawing, and an actual reduction to practice were first introduced into the United States, and (c) diligence began in the United States.

When the APJ substituted Count 2 for Count 1, he instructed the parties that "[b]ecause the count has been broadened, the parties are authorized to file new preliminary statements within six weeks of from [sic] the date of this paper. If no new preliminary statement is filed, it will be presumed that the party intends to rely [o]n its previously filed preliminary statement." Motions Decisions at 55. On or about February 20, 2001, Martin filed an "amended" preliminary statement[44] reciting earlier dates and different acts than are alleged in the first

[44] Paper No. 130.

preliminary statement. For example, the amended preliminary statement alleges (at 2, ¶ 10) that "a drawing of the invention was first introduced in the United States of America: at least by April 13, 1981 (the date of the U.S. application basing priority on the application for Exhibit A." Exhibit A, submitted with the amended preliminary statement, is a copy of the Martin '122 Canadian patent. The amended preliminary statement (at 3, n.1) gave the serial number of the U.S. application as 06/254,019 and indicated that efforts were under way to locate a copy of that application. A copy of the '019 application was filed on or about April 2, 2001. The amended preliminary statement gives May 8, 1980, as the date an actual reduction to practice was introduced into the United States (at 3, ¶ 14).

Twardowski contends[45] that the amended preliminary statement is unauthorized because the pre-1989 dates and acts recited therein relate only to Count 2's Alternative A, which is identical to Count 1, and therefore should have been recited in the first preliminary statement, which was directed to Count 1. Twardowski would have us restrict Martin to the 1989 dates alleged in the first preliminary statement. We need not decide

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[45] "Twardowski's Motion to Suppress Martin's Priority Evidence [MR 8-215 and MX 1-84] and Related Arguments in Its Opening Brief Pursuant to 37 C.F.R. § 1.656(h)" (Paper No. 203), at 8-17.

this question, because Martin's priority evidence is insufficient for the reasons given above whether or not Martin is restricted to the dates alleged in the first preliminary statement.

(d) Whether Martin's priority evidence must fall within the scope of Martin's involved claims and disclosure

Twardowski argues that Martin's priority evidence should be suppressed because it does not fall within the scope of Martin's involved claims and disclosure, citing Lee v. Hotten, 205 USPQ 559, 563 (Bd. Pat. Int. 1976) and Clarke v. Schempp, 140 USPQ 430, 433 (Bd. Pat. Int. 1963). In view of our determination that Martin's priority evidence fails to satisfy the requirements of Alternative A of Count 2, we need not decide this question. We note in passing, however, that this question has yet to be resolved. See Langere v. Crompton, 211 USPQ 917, 918 (Comm'r Pat. 1980):

> [A]s Langere et al. point out in their petition, the Squires [v. Corbett, 560 F.2d 424, 194 USPQ 513 (CCPA 1977)] case cited by the Examiner supports the proposition that the count, rather than the corresponding claim, "effectively circumscribes the interfering subject matter, thereby determining what evidence will be regarded as relevant on the issue of priority" (194 USPQ at 519). Whether or not a party may establish prior invention based upon work which falls within the counts, but not within his disclosure and/or claims, seems to be somewhat of an open question at this time; compare the above-quoted statement from the Squires case with Clarke v. Schempp, 140 USPQ 430 (Bd. Pat. Int. 1963) and Lee v. Hotten v. Kreutzer, 205 USPQ 559 (Bd. Pat. Int.

(Last Depo. at MR 57, ll. 14-17; MR 58, ll. 7-13). The parties agree that these pre-1983 activities therefore are attributable to Mr. Martin acting as a sole inventor. See Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994)("A joint invention is the product of a collaboration between two or more persons working together to solve the problem addressed. 35 U.S.C. § 116 (1988); Kimberly-Clark Corp. v. Procter & Gamble Distrib., Co., 973 F.2d 911, 917, 23 USPQ2d 1921, 1926 (Fed. Cir. 1992)."); Perkins v. Engs, 118 F.2d 924, 928, 49 USPQ 247, 251 (CCPA 1941)("The question of priority [with respect to appellants who are joint inventors] must be determined from the beginning of the joint activities of appellants."). Twardowski has moved to suppress the evidence of these pre-1983 activities because they relate to sole invention by Mr. Martin rather than to joint invention by Messrs. Martin and Last, the inventive entity named in the amended preliminary statement. See Perkins, 118 F.2d at 929, 49 USPQ at 251 ("In an interference proceeding a party (Perkins and Davies) cannot overcome the prior date of its adversary (Engs and Moravec) by proving that a third party (Perkins) was in effect the inventor.").

Martin counters that the reliance on Mr. Martin's sole activities is proper because

> [b]oth Geoffrey S. Martin and Jonathan E. Last are inventors of the invention defined by the Count. Geoffrey S. Martin is the sole inventor for an embodiment within the scope of the Count as it relates to Alternative A. Martin never hid this fact, making it clear in its submitted declarations [MR 15-16, ¶ 1, 4-6 (Martin)]; [MR 21, ¶ 2-3 (Last)], and even emphasizing this fact during Mr. Last's deposition, when counsel for Martin asked whether he was involved in the design or development of the SC-400. [Fact 80]. Moreover, the attachment of the Canadian '122 patent [as Exhibit A] to the Amended Preliminary Statement makes it clear that Martin always presented Geoffrey S. Martin as the sole inventor as to one alternative of the Count (Alternative A) to which the earliest dates applied. [Footnote omitted.]

MRBr. 13. This reliance on Martin's and Last's priority declarations and Last's deposition testimony to interpret the amended preliminary statement is clearly misplaced, as the meaning of the statement should be clear as of its filing date. Dewey v. Lawton, 347 F.2d 629, 146 USPQ 187 (CCPA 1965), explains:

> As Rivise & Caesar point out, in 1 Interference Law and Practice § 86 (1940), "The purpose of requiring preliminary statements from the parties to an interference is to obtain from them an honest statement of the essential facts and dates upon which they may have to rely to prove priority of invention."

347 F.2d at 630-31, 146 USPQ at 188. One of these essential facts is the identification of the inventive entity who made the subject matter of the count, which is required by 37 CFR § 1.622(a):

> (a) A party's preliminary statement must identify the inventor who made the invention defined by each count and must state on behalf of the inventor the facts required by paragraph (a) of §§ 1.623, 1.624, and 1.625 as may be appropriate.

See also Fisher v. Gardiner, 215 USPQ 620, 623 (Bd. Pat. Int. 1981), wherein Fisher moved to amend the preliminary statement to change the named inventors from Fisher and Speer to Fisher and Hill:

> The primary reason that a party is required to act diligently to correct the misjoinder of inventors in an interference context is so that his opponent will know the correct name of the party's inventive entity and thereby know whom the party can or cannot rely upon as a corroborating witness for conception, reduction to practice, etc. Manny v. Garlick, 135 F.2d 757, 57 USPQ 377 (CCPA 1943); Willis v. Suppa v. Koehler, 209 USPQ 406 (Bd. Pat. Intf. 1980).

Fisher's motion to amend was approved in part because it was filed "before Fisher et al. took any testimony that they were relying on the inventive entity of Fisher and Hill." 215 USPQ at 623.

The party Martin's reliance on its priority testimony to interpret its preliminary statement is therefore improper because it contravenes the notice function of the preliminary statement.

Martin's reliance on Exhibit A to the amended preliminary statement (i.e., the Martin '122 Canadian patent) is likewise misplaced, because § 1.629(d) provides that "[t]he content of any drawing or written description submitted with a preliminary

statement will not normally be evaluated or considered by the Board."

Consequently, the question of whether Martin's amended preliminary statement should be understood as identifying Mr. Martin as a sole inventor must be decided based solely on the assertions in the statement itself. We begin by noting that in contrast to the preliminary statements at issue in Credle v. Bond, 25 F.3d 1566, 30 USPQ2d 1911 (Fed. Cir. 1994) and Lawson v. Enloe, 26 USPQ2d 1594, 1596-97 (Bd. Pat. App. & Int. 1992), which employed the conjunctive "and" in naming the inventors but gave nonoverlapping dates for their individual inventive activities, Martin's amended preliminary statement uses the conjunctive "and" without reciting nonoverlapping dates or making any other assertion that is facially inconsistent with joint inventorship. Specifically, in Credle the Court was asked to review the Board's conclusion that the recited nonoverlapping dates were inconsistent with the conjunctive "and," with the result that the preliminary statement is indefinite and subject to the provision in § 1.629(a) that

> [d]oubts as to definiteness or sufficiency of any allegation in a preliminary statement or compliance with formal requirements will be resolved against the party filing the statement by restricting the party to its effective filing date or to the latest date of a period alleged in the preliminary statement, as may be appropriate.

The Court disagreed:

> By focussing entirely on the conjunctive inventorship statement -- "The invention of Count 1 . . . was made by [Credle] and [Boone]" (emphasis added) -- however, the Board gave no weight to the other averments in the preliminary statement which, on their face, disprove the possibility of joint inventorship of this particular count.

Credle, 25 F.3d at 1574, 30 USPQ2d at 1917. The Court explained that

> where the sets of dates alleged define distinct, non-overlapping periods, the allegation that the inventors are joint is facially inconsistent with the two distinct periods, because a person who first conceived and first reduced the subject matter of the invention to practice cannot, under the law, be a joint inventor with a person who allegedly did not even conceive the invention until after the former's reduction to practice.

25 F.3d at 1574, 30 USPQ2d at 1918. Under these circumstances, the Court concluded, "the individual dates averred as to the crucial § 1.623(a) inventive activities wholly undercut any notion that joint inventorship could be inferred from Credle's conjunctive inventorship statement under § 1.622(a)" (footnote omitted). Id. However, after stating that it likewise disagrees with the Board's similar reasoning in Lawson, which involved facts similar to those in Credle, the Court expressly declined to decide the question now before us, which is whether the use of the conjunctive in the absence of an assertion of inconsistent

dates or other facts should be construed as an assertion of joint inventorship:

> We are not bound by the Board's decision in Lawson v. Enloe, 26 USPQ2d 1594, 1596-97 (Bd. Pat. App. & Interf. 1992), which attributed joint inventorship to a comparable conjunctive inventorship statement under similar circumstances. Also, we need not decide whether a conjunctive inventorship assertion alone, even in the absence of an explicit reference to "joint" inventorship, necessarily equates with an allegation of joint inventorship when the dates alleged do not prohibit such an assertion.

25 F.3d at 1576 n.22, 30 USPQ2d at 1919 n.22. We believe this question should be answered in the affirmative, particularly where, as here, the preliminary statement also fails to make any non-date assertion which is inconsistent with joint inventorship.

We therefore agree with Twardowski that Martin's amended preliminary statement should be understood as reciting only joint inventorship by Messrs. Martin and Last, with the result that the party Martin (namely, Geoffrey Martin and Jonathan Last) may not rely on activities representing sole invention by Mr. Martin. Inasmuch as the only activities offered to prove Martin's priority case are sole activities by Mr. Martin, judgment on the issue of priority is being entered below against the party Martin on this ground as well as for failing to prove prior invention of a catheter satisfying the "generally U-shape" requirement.

(f) Whether Martin's abandoned, non-copending application can be relied on as a constructive reduction to practice

The Martin '019 application (MX 1) which Martin cites as a constructive reduction to practice of the subject matter of Alternative A of Count 2 was abandoned in 1982 and thus lacks copendency with the U.S. application (filed April 4, 1991) that matured into Martin's involved '592 patent or with any intervening application. Presumably due to this lack of copendency, Martin explains that "Martin is not relying on the filing date of the '019 application to support an earlier effective filing date of Martin's '592 patent in interference" (MBr. 54).[46] Instead, Martin argues that Rexam Indus. Corp. v. Eastman Kodak Co., 182 F.3d 1366, 51 USPQ2d 1457 (Fed. Cir. 1999), recognizes a right to rely on an abandoned, noncopending application as a constructive reduction to practice:

> The filing of a patent application serves as conception and reduction to practice of the subject matter described in the application. Yasko Kawai v.

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[46] Consistent with this assertion, Martin did not file a § 1.633(f) motion to obtain the benefit of the filing date of the '019 application, as required by 37 CFR § 1.630:

> A party shall not be entitled to rely on the filing date of an earlier filed application unless the earlier application is identified (§ 1.611(c)(5)) in the notice declaring the interference or the party files a preliminary motion under § 1.633 seeking the benefit of the filing date of the earlier application.

> Metlesics, 480 F.2d 880, 885, 178 USPQ 158, 162 (CCPA 1973). This rule is maintained even if the patent application is later abandoned where the patent application itself is not being utilized for its co-pendency. Rexam Industries Corp. v. Eastman Kodak Co., 182 F.3d [1]366, 51 USPQ2d 1457 (Fed. Cir. 1999).

MBr. 53. This argument mischaracterizes Rexam and its relationship to In re Costello, 717 F.2d 1346, 219 USPQ 389 (Fed. Cir. 1983), which is addressed in Rexam and concerns an applicant's attempt to antedate a prior art reference by relying on an abandoned, noncopending application as a constructive reduction to practice under 37 CFR § 1.131. Costello held that the lack of copendency precluded the abandoned application from serving as a constructive reduction to practice:

> Appellants' principal contention is that the filing of the later abandoned original application constitutes a constructive reduction to practice of the invention. Appellants cite no authority, nor can they, to support their argument. It has long been settled, and we continue to approve the rule, that an abandoned application, with which no subsequent application was copending, cannot be considered a constructive reduction to practice. It is inoperative for any purpose, save as evidence of conception. [Footnote 13 is reproduced infra.]
>
> While the filing of the original application theoretically constituted a constructive reduction to practice at the time, the subsequent abandonment of that application also resulted in an abandonment of the benefit of that filing as a constructive reduction to practice. The filing of the original application is, however, evidence of conception of the invention.

Costello, 717 F.2d at 1350, 219 USPQ at 391-92. That the foregoing principles also apply in an interference context is

evident from the fact that footnote 13 cites interference decisions as support for the proposition that an abandoned, noncopending application is inoperative for any purpose, save as evidence of conception. That footnote reads:

> Carty v. Kellogg, 7 App. D.C. 542, 1896 C.D. 188 (1896). Carty involved a fact situation almost identical to the present case. Carty filed an original application April 20, 1885, which was abandoned October 21, 1887. Kellogg filed an application July 30, 1887. Subsequently, on November 17, 1887, Carty filed a second application. An interference was generated and Carty tried to rely on the abandoned application as a constructive reduction to practice in order to establish priority. The Court of Appeals for the District of Columbia stated:
>
> "Failing in proof of actual reduction, Carty is forced to rely upon constructive reduction to practice, and, in order to antedate Kellogg, he claims it by virtue of his abandoned application of 1885. It seems to be a reasonable and well-established principle, conformed to in the practice of the Patent Office, that an abandoned application cannot be so considered. (Hien v. Pung, C.D., 1894, 92; 68 O.G., 657.) Having lapsed, it becomes inoperative for any purpose, save as evidence of the date of conception, and to that extent it has already been considered and its weight admitted." 1896 C.D. at 191.

Costello, 717 F.2d at 1350 n.13, 219 USPQ at 391 n.13. See also Anderson v. Walch, 152 F.2d 975, 977, 68 USPQ 215, 217 (CCPA 1946)("The two applications were not copending. Accordingly, appellant is entitled to the filing date of his original application for conception of the invention, but is not entitled to that date for [a] constructive reduction to practice."); and C. Rivise & A. Caesar, I Interference Law and Practice § 162, at

510 (The Michie Co. 1940):

> The sixth prerequisite for a constructive reduction to practice is that from the filing date of the application relied upon to the filing date of the application directly involved in the interference, there must always have been pending an application containing adequate basis for the subject matter in controversy. In other words, there must never have been a hiatus or interruption in the continuity of applications upon which the interferent may have relied.

Rexam not only failed to create an exception to the foregoing rule under the circumstances presented by the present interference, it does not even involve reliance on an abandoned, noncopending application as a constructive reduction to practice. Rexam concerned two interferences: (a) Interference No. 102,667 ("the '667 interference") between Rexam Patent 4,931,324 and Kodak Application 07/609,050 ("Kodak '050"); and (b) Interference No. 103,738 ("the '738 interference") between Avery Application 08/419,837 and Kodak '050. In both interferences, Kodak relied on the November 3, 1987, filing date of "a parent application" as a constructive reduction to practice to antedate Rexam's earliest asserted date of invention. Rexam, 182 F.3d at 1367-68, 51 USPQ2d at 1458. PTO records identify Kodak '050, which was filed on November 2, 1990, as a file wrapper continuation (FWC)

of Application 07/116,426 ("the '426 application"), filed on September 3, 1987, and abandoned on the November 2, 1990, filing date of Kodak '050.

Rexam did not deny that the '426 application and Kodak '050 were copending. Instead, Rexam argued that for other reasons Kodak had effectively abandoned the right to continue to rely on the '426 application as a constructive reduction to practice in the '667 interference. More particularly, in the '738 interference, the Board awarded priority to Avery on the ground that Avery had proved a date of invention prior to Kodak's constructive reduction to practice date (i.e., the filing date of the '426 application). In the '667 interference the Board entered judgment on the issue of priority in favor of Kodak on the ground that Kodak's constructive reduction to practice date (namely, the filing date of the '426 application) antedates Rexam's asserted date of invention. Rexam, 182 F.3d at 1367-68, 51 USPQ2d at 1458.

Kodak did not seek judicial review of the adverse decision in the '738 interference. In a 35 U.S.C. § 146 action brought by Rexam for review of the Board's adverse decision in the '667 interference, the district court certified a number of questions which became the basis of the appeal to the Federal Circuit. In that appeal, Rexam argued that Kodak's failure to appeal the loss

to Avery in the '738 interference is "tantamount to an abandonment" of the '050 application and quoted Costello's holding that an abandoned application "is inoperative for any purpose, save as evidence of conception." Rexam, 182 F.3d at 1370, 51 USPQ2d at 1460. The Court rejected this reliance on Costello:

> Costello is not pertinent. The issue in Costello concerned an applicant's attempt to traverse a rejection made pursuant to 35 U.S.C. § 103 by relying on the filing date of an earlier application that the applicant had abandoned with no corresponding application copending at the time of abandonment. See Costello, 717 F.2d at 1347-48, 219 USPQ at 390. Costello thus lost because of a lack of copendency; in that case, we stated that "we continue to approve the rule, that an abandoned application, with which no subsequent application was copending, cannot be considered a constructive reduction to practice." Id. at 1350, 219 USPQ at 391. Rexam's reliance on Costello is therefore misplaced, because this is not a case of a lack of copendency where copendency is needed to retain entitlement to a filing date.

Rexam, 182 F.3d at 1370, 51 USPQ2d at 1460. In other words, the Court held Costello to be inapposite to the Rexam facts because the required copendency that was lacking in Costello was present in Rexam insofar as Kodak's reliance on the '426 application as a constructive reduction to practice was concerned. Thus, Rexam does not support Martin's contention that an earlier application can serve as a constructive reduction to practice even where copendency is lacking.

Nor are we persuaded by Martin's argument that

> Rexam argued that . . . allowing the abandoned patent application to preclude the patentability of its claims would erroneously create a category of non-statutory prior art, namely, abandoned and non-allowable patent applications, but the Court disagreed, stating that "[t]he flaw in Rexam's logic is that Kodak's patent application is not a new class of prior art; it was a constructive reduction to practice when it was filed. It evidenced a prior invention, which deprives a later invention of patentability. See 35 U.S.C. § 102(g)(1994)." Rexam, 182 F.3d at 1371, 51 USPQ2d at 1461.

MBr. 53-54. The Court's statement that "Kodak's patent application . . . was a constructive reduction to practice when it was filed" must be viewed in the presence of the copendency required for a constructive reduction to practice. Because this copendency was present, it was not necessary for the Court to mention the principle that "[w]hile the filing of the original application theoretically constitute[s] a constructive reduction to practice at the time, the subsequent abandonment of that application . . . result[s] in an abandonment of the benefit of that filing as a constructive reduction to practice." Costello, 717 F.2d at 1350, 219 USPQ at 391-92.

The lack of copendency between the '019 application and the application that matured into the involved Martin '592 patent is therefore another reason the party Martin may not rely on the

'019 application as a constructive reduction to practice of the subject matter of Alternative A of Count 2.

(g) Whether Martin recognized and appreciated the "generally U-shape" feature

In view of the above deficiencies in Martin's priority case, it is not necessary to address the merits of Twardowski's argument that the evidence fails to show that Martin recognized or appreciated the existence of an invention in the generally U-shaped configuration, in support of which proposition Twardowski cites Rosco, Inc. v. Mirror Lite, Co., 304 F.3d 1373, 1381, 64 USPQ2d 1676, 1682 (Fed. Cir. 2002)(citing Estee Lauder, Inc. v. L'Oreal, S.A., 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997)).

(h) Whether the SC-400 catheter was abandoned, suppressed or concealed

Martin's failure to prove an actual reduction to practice also makes it unnecessary to consider Twardowski's argument that the invention was abandoned, suppressed or concealed subsequent to an actual reduction to practice.

(i) Summary of Martin's priority case

Because Martin has failed to prove either the alleged construction reduction to practice or the alleged actual reduction to practice of the subject matter of Alternative A of Count 2, the only inventive acts relied on in Martin's opening

brief, judgment on the issue of priority with respect to the subject matter of Count 2 is being entered infra in favor of Twardowski based on the January 8, 1990, filing date of Twardowski's Canadian benefit application (now Canadian Patent 2,013,877).[47]

F. TWARDOWSKI'S PRIORITY CASE

Twardowski's preliminary statement[48] asserts a conception date of March 1985, an actual reduction to practice date of March 23, 1989, and diligence beginning in March 1985. As all of these dates are subsequent to the dates of invention alleged in Martin's amended preliminary statement, which have not been proved, no purpose would be served by addressing the merits of Twardowski's priority evidence.

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[47] Martin's opening brief does not alternatively rely on the acts or dates asserted in Martin's first preliminary statement.

[48] Paper No. 14.

G. JUDGMENT

Judgment on the issue of priority with respect to Count 2, the sole pending count, is hereby entered against junior party Martin (Geoffrey S. Martin and Jonathan E. Last) and in favor of senior party Twardowski (Zyblut J. Twardowski, John C. Van Stone, and W. Kirt Nichols). Accordingly, senior party Twardowski is entitled to a patent including its application claims which correspond to the count (namely, claims 1 and 19-38) and junior party Martin is not entitled to a patent including any of its patent claims which correspond to the count (namely, claims 1-19).

STANLEY M. URYNOWICZ, JR.
Administrative Patent Judge)

WILLIAM F. PATE III
Administrative Patent Judge)

JOHN C. MARTIN
Administrative Patent Judge)

BOARD OF
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JCM/cam

Appendix A -- Twardowski's involved application claims

1. A catheter for hemodialysis which comprises a flexible catheter tube defining a plurality of separate lumens, said catheter defining an arc angle of generally U-shape in its natural, unstressed configuration, whereby said catheter may be implanted with a distal catheter portion residing in a vein of a patient, said distal catheter portion being of substantially the shape of said vein in its natural, unstressed condition, and a proximal catheter portion residing in a surgically created tunnel extending from said vein and through the skin of the patient, whereby blood may be removed from said vein through one lumen of the catheter and blood may be returned to said vein through another lumen of the catheter.

19. A flexible catheter for prolonged vascular access, the catheter comprising: an elongate flexible and tubular body having a proximal portion, a distal portion and a permanently curved portion linking the proximal and distal portions so that the curved, the proximal and the distal portions lie naturally in essentially the same plane with the angle contained between the proximal and distal portions being less than 90°, and a septum extending continuously through said portions and lying substantially at right angles to said plane to divide the tubular body into generally D-shaped intake and outlet lumens; intake and outlet tubes coupled to the proximal portion at a proximal end of the body remote from the curved portion to receive incoming fluid from the intake lumen and to supply outgoing fluid to the outlet lumen; and a tip formed on the distal end of the distal portion and including at least one intake opening for receiving the incoming fluid and at least one outlet opening for returning the outgoing fluid.

20. The flexible catheter of claim 19 in which said portions are round in cross-section.

21. The flexible catheter of claim 20 in which the diameter of the proximal portion is greater than the diameter of the distal portion.

22. The flexible catheter of claim 21 further comprising a cuff of fibrous material surrounding the body where the proximal portion meets the curved portion.

23. The flexible catheter of claim 20 further comprising a cuff of fibrous material surrounding the body where the proximal portion meets the curved portion.

24. The flexible catheter of claim 19 further comprising a cuff of fibrous material surrounding the body where the proximal portion meets the curved portion.

25. The flexible catheter of claim 19 in which the tip includes an extension blending smoothly into the body and forming an extension to the outlet lumen.

26. The flexible catheter of claim 25 in which the at least one intake opening is at a side of the distal portion facing the proximal portion, and in which the extension is at a side of the distal portion remote from the proximal portion.

27. The flexible catheter of claim 26 in which said portions are round in cross-section.

28. The flexible catheter of claim 27 in which the diameter of the proximal portion is greater than the diameter of the distal portion.

29. The flexible catheter of claim 28 in which said angle is in the range of 0°-20°.

30. The flexible catheter of claim 26 further comprising a cuff of fibrous material surrounding the body where the proximal portion meets the curved portion.

31. The flexible catheter of claim 19 in which the at least one intake opening is at a side of the distal portion facing the proximal portion, and in which the outlet opening is at a side of the distal portion remote from the proximal portion.

32. The flexible catheter of claim 31 in which said portions are round in cross-section.

33. The flexible catheter of claim 32 in which the diameter of the proximal portion is greater than the diameter of the distal portion.

34. The flexible catheter of claim 33 in which said angle is in the range of 0°-20°.

35. The flexible catheter of claim 31 further comprising a cuff of fibrous material surrounding the body where the proximal portion meets the curved portion.

36. The flexible catheter of claim 19 in which the distal portion is sufficiently flexible to be deformed readily to follow the shape of a vein after entry, and in which the proximal portion is more rigid than the distal portion.

37. The flexible catheter of claim 19 in which said angle is in the range of 0° to 20°.

38. A flexible catheter for prolonged vascular access, the catheter comprising: an elongate flexible and tubular body having a proximal portion, a distal portion and a permanently curved portion linking the proximal and distal portions so that the curved, the proximal and the distal portions lie naturally in essentially the same plane with the angle contained between the proximal and distal portions being less than 90°; intake and outlet tubes coupled to the proximal portion at a proximal end of the body remote from the curved portion to receive incoming fluid from the intake lumen and to supply outgoing fluid to the outlet lumen; and a tip formed on the distal end of the distal portion and including at least one intake opening for receiving the incoming fluid and at least one outlet opening for returning the outgoing fluid.

Appendix B -- Twardowski's originally filed application claims

1. A catheter for hemodialysis which comprises a flexible catheter tube defining a plurality of separate lumens, said catheter defining an arc angle of generally U-shape in its natural, unstressed configuration, whereby said catheter may be implanted with a distal catheter portion residing in a vein of a patient, said distal catheter portion being of substantially the shape of said vein in its natural, unstressed condition, and a proximal catheter portion residing in a surgically created tunnel extending from said vein and through the skin of the patient, whereby blood may be removed from said vein through one lumen of the catheter and blood may be returned to said vein through another lumen of the catheter.

2. The catheter of Claim 1 which defines, in its natural unstressed condition, a second arc section which bends in the dimension perpendicular to the dimension of the U-shape of said catheter.

3. The catheter of Claim 2 in which said second arc section defines an arc angle of essentially 50-90 degrees.

4. The catheter of Claim 1 which carries a spaced pair of tissue securance cuffs along its proximal portion for implantation in said surgically-created tunnel.

5. The catheter of Claim 1 in which the pair of spaced catheter lumens terminate at distal ends in, respectively, first and second ports, said second port being positioned proximally of said first port to permit simultaneous withdrawal of blood from, and infusion of blood to said vein while minimizing recirculation of blood through the catheter.

6. A catheter for access to the vein of a patient, said catheter comprising a flexible catheter tube having at least a pair of separate lumens for respectively withdrawing blood from said vein and returning blood thereto, said catheter defining relatively straight end portions, plus a central portion which defines, in its natural, unstressed configuration a U-shaped section, plus a second, curved section connected to said U-shaped section, which second section bends in an arc which extends in the dimension perpendicular to said U-shaped section, whereby said catheter may be implanted with a distal portion thereof occupying a vein and being of substantially the shape of said

vein, and a proximal portion thereof which occupies a surgically-created tunnel extending from said vein through the skin of the patient, while said catheter occupies substantially its natural, unstressed shape.

7. The catheter of Claim 6 in which a third curved section of said catheter is defined, in its natural, unstressed configuration, said third bend being positioned between said second curved section and the distal catheter end.

8. The catheter of Claim 6 in which said catheter distal portion is of a length sufficient to permit the positioning of the catheter distal end in the right atrium of the patient's heart while the catheter enters the patient's venous system through the left jugular vein.

9. The catheter of Claim 1 in which said catheter distal portion is of a length sufficient to permit the positioning of the catheter distal end in the right atrium of the patient's heart while the catheter enters the patient's venous system through a jugular vein.

10. The catheter of Claim 1 in which said catheter distal portion is of a length sufficient to permit the positioning of the catheter distal end in the right atrium of the patient's heart while the catheter enters the patient's venous system through a subclavian vein.

11. The catheter of Claim 1 in which a distal portion of said arc angle defining said U-shape of the catheter defines a second arc angle projecting in the dimension perpendicular to the arc angle of said U-shape.

12. The catheter of Claim 1 in which, in said natural, unstressed configuration, said U-shape defines a central arc angle between a pair of relatively straight terminal catheter sections, the terminal catheter section which is the distal portion of said catheter bending forwardly in the dimension perpendicular to said U-shaped arc angle of the catheter.

13. In a method of simultaneously withdrawing and replacing blood from a patient making use of an implanted catheter, the improvement comprising, in combination, implanting said catheter in the patient with a proximal portion of the catheter extending through a surgically created tunnel and a distal portion of said

catheter extending through the venous system of said catheter [sic, patient], with the distal tip of said catheter occupying the right atrium of the heart, said catheter occupying a substantially unstressed, as-manufactured configuration in both said venous system and said surgical tunnel.

14. The method of Claim 13 in which said catheter in its unstressed, as-manufactured configuration is of substantially U-shape with a central catheter arc and a pair of relatively straight catheter end portions, one of said catheter end portions occupying the venous system of said patient; the other of said end portions occupying the surgically created tunnel of said patient; said catheter penetrating the wall of a vein of said venous system at a position along said U-shaped arc.

15. A catheter for hemodialysis which comprises a flexible catheter tube having a distal end and defining a plurality of separate lumens, said catheter defining a first arc angle in its natural, unstressed configuration, said first arc angle being spaced from the catheter distal end, said catheter also defining, in its natural, unstressed condition, a second arc angle positioned between said first arc angle and said distal end, said second arc angle extending in a direction substantially opposed to the direction of said first arc angle.

16. The catheter of Claim 15 which is proportioned for implantation into the patient through the femoral vein, said catheter being of a length to permit positioning of the distal catheter end in the inferior vena cava, said catheter defining a shape in its natural, unstressed condition which is of the shape of the venous system in which said catheter is implanted.

17. The catheter of Claim 16 in which said first arc angle is of essentially 10° to 50°, and extending essentially 50-200 mm., said second arc angle defining an arc of essentially 20° to 50° and extending essentially 20-50 mm.

18. The catheter of Claim 15 in which said first arc angle is of essentially 10° to 50°, and extending essentially 50-200 mm., said second arc angle defining an arc of essentially 20° to 50° and extending essentially 20-50 mm.